Studie 034

(M-2020-0034)

Studienbericht

Reboxetine (PNU-155950E) vs. placebo in the treatment of major depressive disorder resistant to fluoxetine

Final Report of the Trial
M-2020-0034

Previous Reports of the Trial:
None

It is the policy of Pharmacia to conduct clinical trials in compliance with company SOPs and Standards which incorporate the requirements of the ICH Guideline for Good Clinical Practice. These include trial conduct and archiving of essential documents. Protocol deviations are described in this report.

Trial Initiation Date	June 17, 1999
Trial Completion Date	June 5, 2000
Sponsor's Responsible Medical Officer	Saeeduddin Ahmed, M.D. U. S. Medical Affairs Pharmacia Corporation Kalamazoo, Michigan
Development Phase of Trial	Phase III-B
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1. SIGNATURE PAGE

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2. SYNOPSIS

Name of Company: Pharmacia Corporation **Name of Finished Product:** VESTRA **Name of Active Ingredient:** Reboxetine mesylate	**Individual study table**	(For national authority use only)

Title of study:

Reboxetine (PNU-155950E) vs placebo in the treatment of major depressive disorder resistant to fluoxetine

Protocol number:
M-2020-0034

Investigators and Study Centers:

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Publication (reference):

Studied period (years):
Date of first enrollment: June 17, 1999
Date last completed: June 5, 2000

Phase of development:
IIIb

Objectives:
The primary objective was to compare the safety and efficacy of reboxetine vs placebo in the treatment of patients suffering from a Major Depressive Disorder resistant to fluoxetine treatment but responsive to open-label reboxetine. A secondary objective was to assess the safety and determine the response rate of open-label reboxetine treatment in fluoxetine resistant patients with Major Depressive Disorder.

Name of Company: Pharmacia Corporation **Name of Finished Product:** VESTRA **Name of Active Ingredient:** Reboxetine mesylate	**Individual study table**	(For national authority use only)

Methodology:
The design of this trial was a double-blind discontinuation trial with survival analysis of reboxetine vs placebo in patients who have failed fluoxetine but responded to open-label reboxetine. This phase IIIb study was carried out in 28 centers. Adult patients were selected from the attending out-patient populations or recruited from the communities. Eligible patients with Major Depressive Disorder (MDD) who had not responded to open-label fluoxetine treatment according to the subject inclusion criteria were treated with open-label reboxetine for eight weeks. Patients who responded to the 8 week open-label reboxetine treatment (Part 1) were randomized in double-blind fashion to continue the Day 57 dose of reboxetine or to begin placebo treatment (Part 2). Reboxetine non-responders were withdrawn from the study at or before Day 57. After randomization, treatment was continued until the patient had evidence of relapse of MDD, completed 6 months of treatment without relapse or withdrew for other reasons. Efficacy and safety evaluations were conducted at regular intervals throughout both open-label and post-randomization treatment phases.

Number of patients (planned and analyzed):
Planned: 200 patients were scheduled to be enrolled in Part 1 to yield approximately 87 patients to be randomized in Part 2; Analyzed: 128 patients in Part 1 and 47 patients in Part 2

Diagnosis and main criteria for inclusion:
Part 1: Patients must have had a Diagnostic and Statistical Manual-IV (DSM-IV) diagnosis of Major Depressive Disorder (MDD) without Psychotic Features. Further, they must have been non-responders (i.e., must have had a Clinical Global Impression rating of "minimally improved" to "very much worse") for each of the last two weeks of six to 12 weeks of open-label fluoxetine treatment. All patients must have provided signed, written informed consent. Patients failing to respond to 8-weeks of treatment with open-label reboxetine were withdrawn from the study at the end of part 1. Response in Part 1 was defined as ≥50% reduction in the total 25-item HAMD score at Day 57 as compared to Day 1 and CGI improvement score of 1 or 2. Failure to respond was defined as <50% reduction in the total 25-item HAMD score at Day 57 as compared to Day 1 or a CGI improvement score of 3 to 7.
Part 2: Responders to reboxetine in Part 1 were randomized to continued treatment with reboxetine or placebo and treated for 6 months or until such time as they had relapsed (defined as a ≥50% increase of the 25-item HAMD total score and a minimum total of ≥10).

Test product, dose and mode of administration, batch number:
Reboxetine mesylate tablets, 4 mg (lot 28,439)

Duration of treatment:
Part 1: 8 weeks; Part 2: maximum of 6 months

Reference therapy, dose and mode of administration, batch number:
Part 1: none; Part 2: Placebo (lot 28,449)

Name of Company: Pharmacia Corporation **Name of Finished Product:** VESTRA **Name of Active Ingredient:** Reboxetine mesylate	**Individual study table**	(For national authority use only)

Criteria for evaluation:

Efficacy: Primary Efficacy Variable: Rate of relapse of reboxetine vs placebo during long term treatment in patients who responded to open-label treatment with reboxetine during 8 week treatment period. Relapse of MDD was defined as $\geq$ 50% increase of 25-item HAMD total score compared to the Day 57 (week 8) HAMD total score, and a minimum HAMD total score of $\geq$ 10 (on the 25-item HAMD). Response during open-label treatment was defined as ≥50% decrease in the 25-item Hamilton Rating Scale for Depression (HAMD) total score and a CGI improvement score of 1 or 2.

Secondary Efficacy Variables: (1) Hamilton Rating Scale for Depression (HAMD): 25-, 17- and 28-item versions, (2) Montgomery Asberg Depression Rating Scale, (3) Clinical Global Impression, (4) Patient Global Impression, (5) Medical Outcomes Study (SF-36), (6) Social Adaptation Self-evaluation Scale (SASS), (7) Kellner Symptom Questionnaire and (8) Rush Sexual Inventory

Safety: (1) Medical history, (2) Clinical and physical examination, (3) Clinical laboratory evaluations, (4) Vital signs (blood pressure, pulse, weight, respiration, temperature), (5) 12-lead ECG and (6) Adverse event questionnaire

Statistical methods:

The intent-to-treat (ITT) population, which included all patients who were enrolled, received at least one dose of study medication and had at least one postbaseline evaluation, was used for all analyses. Two type of analyses were performed for the efficacy variables: “last observation carried forward” (LOCF) and “observed cases” (OC). The LOCF analysis used the last valid assessment as an estimate for all subsequent missing values. The OC analysis did not replace missing data. The LOCF analysis was considered to be the primary analysis; the OC analysis was the secondary analysis. P-values, based on 2-sided tests, were considered statistically significant if they were less than or equal to 0.049.

Efficacy Results:

The results from Part 1 of this study clearly demonstrate that reboxetine is effective in treating Major Depressive Disorder in patients that have previously failed to respond to fluoxetine therapy. Approximately half of the patients enrolled in this study experienced at least a 50% decrease in their Hamilton Depression Rating Scale (25-item) score at the end of eight weeks of treatment with reboxetine on an open-label basis. Both the “last observation carried forward” (LOCF) and “observed cases” (OC) analyses of the HAMD total scores showed a consistent significant decrease from baseline throughout the eight week treatment period. An appreciable number of individual Hamilton items (ie, symptoms) already showed significant improvement at week 1. Additional improvement was seen at weeks 4 and 8.

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The results from the Montgomery Asberg Depression Rating Scale closely paralleled those of the Hamilton Depression scale, ie, a significant progressive decrease in the score occurred over time in both the LOCF and OC analyses. Overall, the results of the remaining psychometric rating scales were consistent with those reported for the Hamilton Depression and Montgomery Asberg scales. Both the clinician's and patient's global impressions showed a significant progressive therapeutic effect over the eight week study period as did the Kellner Symptom Questionnaire.

Collectively, these data support the conclusion that reboxetine was effective in treating the depression in fluoxetine failures during the eight week study period. For reasons that are not clear, the double blind portion (Part 2) of the study failed to demonstrate a difference between reboxetine and placebo in terms of the rate of relapse during weeks 9 through 32 of the study. Relapse in the two treatment groups occurred at the same rate. There was a suggestion that the two subgroups may have differed in several aspects of their psychiatric history that at least in part explained why these results occurred. Further, the remaining sample size was too small to detect a difference between the treatment groups.

Safety Results:
The switch from fluoxetine to reboxetine was without significant clinical sequelae. The frequency of occurrence of adverse events as well as their qualitative nature appeared to be similar in type and frequency in this study as compared to previous clinical experience with reboxetine.
Adverse events were reported in almost all (97.7%) of the patients in the open label portion of this study. Many of the events (eg, fatigue, , insomnia, etc) reported are also common symptoms of Major Depression and thus may be related to the disease itself. Serious events were reported by five patients in the study, including three in Part 1 and two (reboxetine = 1; placebo = 1) in Part 2. Only one of these was thought to be potentially related to reboxetine treatment.
The most common adverse events occurring in Part 1 were: headache (47.7%), insomnia (47.7%), dry mouth (43.8%), constipation (28.1%) and diaphoresis (26.6%). These events were most commonly reported as mild or moderate in intensity. Most events occurred during the first four weeks of treatment and then sharply decreased. Twenty one patients discontinued from Part 1 of the protocol because of adverse events. The most common event leading to dropout was insomnia. The occurrence of adverse events in Part 2 was only somewhat higher in the reboxetine group (79.2%) as compared to the placebo group (68.2%). There were no specific symptoms that seemed to occur more frequently in the reboxetine group.
There were no changes in clinical laboratory measures that appeared to occur more often in the reboxetine group. Statistically significant changes were small, occurred randomly in time and usually reversed even with continued treatment. Similarly, most of the vital signs recorded during the study exhibited no consistent drug-induced changes. However, pulse rate increased upon initiation of reboxetine treatment and remained elevated throughout the treatment period. Therefore caution is indicated with administering reboxetine to patients with compromised cardiovascular conditions. Further, the rate appeared to decrease in those patients after being randomized to placebo in Part 2. The vital sign data were confirmed by the ECGs recorded during the study.

Conclusion:
The results from Part 1 of the study clearly demonstrated that reboxetine was effective in treating patients who fail fluoxetine treatment. Approximately half of the patients enrolled in this study experienced at least a 50% decrease in their Hamilton Depression Rating Scale score at the end of eight weeks of treatment with reboxetine on an open-label basis. These results were mirrored by those of the Montgomery Asberg Depression Rating Scale as well as the clinician's and patient's global evaluations. The safety evaluations from both parts of this study showed that it is safe to switch immediately from fluoxetine treatment to reboxetine therapy. The occurrence of adverse events were qualitatively and quantitatively similar to those reported in previous reboxetine studies. Only increased pulse occurred consistently during reboxetine treatment. The results from Part 1 show that patients taking fluoxetine may safely switch to reboxetine treatment if needed. However, caution is indicated with administering reboxetine to patients with compromised cardiovascular conditions. Part 2 of the study failed to show statistically significant superiority of reboxetine over placebo in terms of the time to relapse during double blind treatment. It is possible that this result is due to the small number of patients (46) randomized in Part 2. These results are in contrast to a previous study which clearly showed that reboxetine is significantly more effective than placebo in preventing relapse from MDD. The reason(s) for the difference in results cannot be completely explained at this time. **Date of the report:** August 15, 2003

3. TABLE OF CONTENTS

Abbreviations and definition of terms

The following abbreviations are used in this report:

AE	Adverse event
ANOVA	Analysis of variance
BID	Twice daily
CGI	Clinical Global Impression
COSTART	Coding Symbols for a Thesaurus of Adverse Reaction Terms
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
ECG	Electrocardiogram
FLX	Fluoxetine
FU	Follow-up
GI	Gastrointestinal
HAMD	Hamilton Rating Scale for Depression
IEC	Independent Ethics Committee
IRB	Institutional Review Board
ITT	Intent To Treat
KSQ	Kellner Symptom Questionnaire
LOCF	Last observation carried forward
MADRS	Montgomery Asberg Depression Rating Scale
MDD	Major Depressive Disorder
OC	Observed-Cases
PBO	Placebo
PGI	Patient Global Impression
RBX	Reboxetine
SAE	Serious adverse event
SASS	Social Adaptation Self-evaluation Scale
SCID	Structured Clinical Interview for DSM-IV Axis I Disorders
SF-36	Medical Outcomes Study Short Form 36
SSRI	Selective Serotonin Reuptake Inhibitor
TCA	Tricyclic antidepressant
TES	Treatment-emergent symptom
WBC	White blood cell

4. ETHICS

4.1. Institutional Review Board (IRB)

The protocol and all amendments for this trial were reviewed by an Institutional Review Board (IRB).

4.2. Ethical Conduct of the Study

This study was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki.

4.3. Patient Information and Consent

The investigator or one of his/her associates explained the nature, duration, and purpose of the study and the action of the drug to potential subjects so that they were aware of potential risk, inconveniences, and adverse events associated with their participation in the study. Informed consent forms, which were approved by Institutional Review Boards, were signed by potential subjects. Informed consent was obtained 2 to 14 days before the start of the protocol.

5. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

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5.3. Field Monitoring Staff

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5.4. Central Laboratory

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5.5. Central ECG Analysis

Premier Research Worldwide (eResearch Technology)

6. INTRODUCTION

Major Depressive Disorder (MDD) [1] is a common and serious illness. Although effective treatments for this condition exist, between 30 and 40% of patients fail to respond to the first antidepressant medication administered [2]. Selective serotonin reuptake inhibitors (SSRIs) are now the most common medication used for the treatment of MDD [3]. About 33% to 50% of patients who begin a trial of an SSRI are unable to tolerate therapeutic doses or are unresponsive to an adequate trial [4, 5,6]. Treatment options for patients who do not respond to SSRI treatment consist of augmentation therapy, changing to another antidepressant within the same class, or changing to a different class of antidepressant [5,6]. Augmentation therapy is helpful to some patients, but puts them at risk of adverse events related to two or more medications, and of those related to drug-drug interactions. The strategy of switching to another antidepressant within the same class was favored a decade ago when physician choices were primarily limited to tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs), the recent availability of a number of additional classes of antidepressants has lessened the enthusiasm for this strategy. Evidence indicates that a second monotherapy may be more effective if the second drug has a pharmacologic profile distinct from the initial medication [5]. Therefore this strategy is considered by some as the best option for patients who have failed an initial medication trial.
Reboxetine (RBX) is a selective norepinephrine reuptake inhibitor [7]. RBX has no relevant affinity for the serotonin and dopamine uptake sites or for muscarinic, cholinergic or adrenergic receptors. This pharmacologic profile makes RBX a novel agent, and potentially useful for patients who have not responded to other available antidepressants.
RBX has undergone extensive preclinical and clinical evaluation as a potential treatment for Major Depressive Disorder (MDD). The program included four placebo (PBO) controlled short term (4 to 8 week) studies and three uncontrolled short term studies in the adult population. Comparator antidepressants were included in three of the placebo controlled studies. Elderly patients were studied in two uncontrolled, one placebo controlled and one imipramine controlled short term studies. Additionally, long term studies (up to one year) were conducted in both adults and elderly patients. The typical RBX doses ranged from 8 to 10 mg/day in the adult population.
Briefly, the results of these studies were as follows:

- Selection of the RBX dose regimens was accomplished in an early phase II, non randomized, dose-finding study (study 004 [8]), which was adequate to identify the daily dose associated with intolerance in a proportion of patients (12 mg/day) and the daily doses associated with minimal side-effect and maximal response rates (8 and 10 mg/day), although, in view of the non-randomized conditions, no conclusions about dose-response could be drawn. However, further support of the appropriateness of the selected dose regimens is derived from the results of the phase III studies, which show that a dose of

8 mg/day is suboptimal in a proportion of patients in whom increasing the dose to 10 mg/day resulted in clinical response. Daily doses lower than 8 mg are unlikely to be maximally effective.

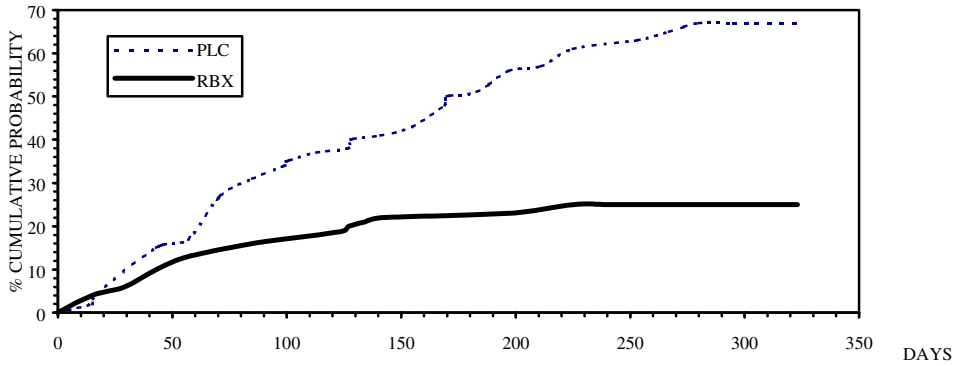
- Three of the PBO -controlled studies (study 091 [9], study 008 [10], study 014 [11]) demonstrated the efficacy of RBX on the study endpoint (ie mean reduction of the Hamilton Rating Scale for Depression {HAMD} total score or response rate is ≥50% decrease in HAMD total score), according to the hypothesis stated in the study protocols. The fourth PBO -controlled study (study 015 [12]) showed greater efficacy for RBX and for IMI than for PBO but the differences between the active treatments and PBO on the study endpoint did not reach statistical significance. However, subpopulation analysis, particularly of the severely ill patients but also of the melancholic patients, showed the efficacy of RBX and IMI on the study endpoint. In the only study completed in the United States as of now (study 049 [13]), a statistically significant difference between RBX and PBO was not reached in the primary efficacy variable (the mean total HAM-D score at day 42; p-value in the observed case analysis {OC} = 0.051). Further, a significant difference in the MADRS total score was found (OC p-value = 0.019; LOCF <0.001). Collectively, these data indicate significant antidepressant activity.

A previous trial with reboxetine (ADE 013) [14] has been conducted with a double-blind discontinuation comparison of reboxetine and placebo in MDD responders to reboxetine. This phase III, PBO -controlled study was conducted to evaluate the long-term maintenance of the response that was obtained during short-term RBX treatment. Acutely ill patients with a recurrence of MDD and a total 21-item HAMD score of 18 or greater received treatment with RBX 4 mg BID for 6 weeks; at the end of this 6 week period, patients who had responded to treatment (≥50% decrease of HAMD total score versus baseline) were randomized to treatment with RBX or PBO until relapse (defined as ≥ 50% increase of HAMD total score versus week 6 associated with a total score of at least 18) occurred or for a maximum treatment period of 1 year.

Three hundred fifty-eight patients were admitted to the study and treated with RBX for 6 weeks; 286 patients (80%) were then randomized to double-blind treatment with RBX (n=145, of which 143 received treatment) or PBO (n=141, of which 140 received treatment). The two groups were similar to the population that was admitted into the study and were well balanced for demographic and baseline characteristics: Females were more common than males in both groups (79% of the patients in the RBX group and 67% of the patients in the PBO group); the average age at admission was 43 years in the RBX group and 42 years in the PBO group. All but one patient was suffering from a recurrence of MDD, with an average number of previous episodes of 3.4 in the RBX group and 3.0 in the PLC group. At admission, the mean duration of the index episode was 13.9 weeks in the RBX group and 15 weeks in the PBO group.

Among the 133 responder patients who were randomized to RBX, 22% relapsed during long-term treatment, whereas, among the 132 responder patients who were randomized to PBO , 56% relapsed; the difference between treatments in relapse rate was statistically significant (p<0.01). The cumulative risk of relapse (Kaplan-Meier analysis) in the 133 and 132 patients who were randomized to RBX and PBO , respectively, and who complied with the protocol response criterion is summarized in Figure 1. Again, the between-treatment difference (log-rank test) was significant (p<0.001).

Figure 1. Cumulative Risk of Relapse*



* Based on Kaplan-Meier methods; N = 132 for PBO and 133 for RBX
Abbreviations: PLC = placebo, RBX = reboxetine

An additional analysis was performed to evaluate the proportion of relapse-free patients during the first and the last 6 months of treatment. The purpose of this analysis was to investigate the rate of relapse of the index episode and the rate of recurrence of a new episode in the two treatment groups. The results of this analysis are summarized in Table 1.

Table 1. Proportion of Relapse-Free Patients After 6 and 12 Months of Treatment

	Reboxetine			Placebo			
		Relapse-Free			Relapse-Free		
Months	N	n*	%	n	n*	%	χ^2 test
1-6	133	81	60.9	132	53	40.2	11.4
7-12	75	66	88.0	49	29	59.2	13.7

* Patients who did not relapse at least once during the indicated period and who did not withdraw because of improvement are included.

Thus, the results of this PBO -controlled study proved the efficacy of RBX in the maintenance therapy of MDD. As measured by the HAMD, MADRS, and CGI scales, RBX was superior to PBO for the maintenance therapy of patients with MDD when administered for up to 1 year.

The current protocol tested the efficacy and safety of RBX in patients with MDD who had not responded to treatment with at least 6 weeks of fluoxetine (FLX). Patients who met the entry criteria of the protocol were immediately switched to open-label RBX for 8 weeks. Subjects who responded to open-label RBX were randomized in double-blind fashion to

continuation therapy with either RBX or placebo (PBO). The primary outcome measure was the rate of relapse in the post-randomization phase.

7. OBJECTIVES

The primary objective was to compare the safety and efficacy of RBX vs. PBO in reducing the rate of relapse in patients suffering from a MDD resistant to FLX treatment but responsive to open-label RBX. A secondary objective was to assess the safety and determine the response rate of open-label RBX treatment in FLX resistant patients with MDD.

8. METHODS

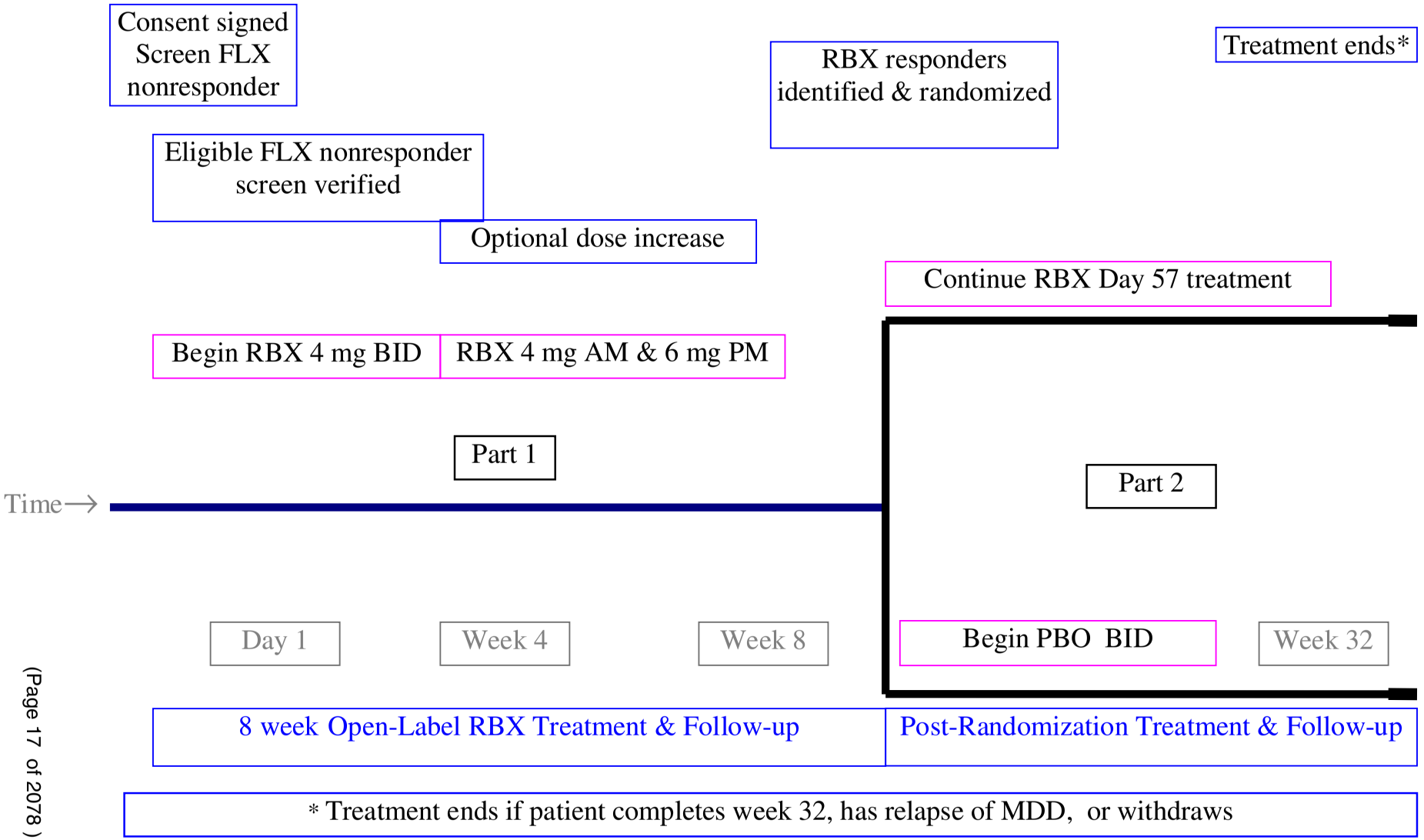
8.1. Overall Study Design and Plan

This protocol consisted of eight weeks of open label RBX treatment (Part 1), followed by a 24-week double-blind discontinuation trial with survival analysis of RBX vs. PBO (Part 2). Adult subjects with MDD were recruited from the community and from outpatients at clinics associated with investigational sites. Patients who had not responded to open-label FLX treatment and met other entry criteria were enrolled in the protocol. In Part 1 of the protocol, subjects were treated with open-label RBX for eight weeks. Treatment started at a dose of 4 mg bid. At the week 4 visit or later, investigators could raise the dose to 4 mg in the morning and 6 mg in the evening (10 mg/day). At the end of Part 1, response was defined as $\geq$ 50% reduction in total 25-item HAMD (25-item Hamilton Depression Rating Scale) score at Day 57 compared to Day 1 and CGI (Clinical Global Impression Scale) improvement of 1 or 2. A HAMD total score of < 7 was considered evidence of remission.

In Part 2, subjects who responded to open-label RBX treatment in Part 1 were randomized in double-blind fashion to either continue RBX or to begin PBO treatment for up to an additional 24 weeks. Subjects who had not responded to open-label RBX treatment were withdrawn from the protocol. After randomization, treatment was continued until individual subjects had evidence of relapse of MDD, completed 32 weeks of combined treatment in Parts 1 and 2 without relapse, or withdrew because of adverse events. Responders who continued in Part 2 had subsequent 25-item HAMD scores compared to the Day 57 HAMD score. The primary endpoint was the rate of relapse of MDD for patients in the post-randomization phase. Relapse of MDD was defined as $\geq$ 50% increase of 25-item HAMD total score compared to the Day 57 (week 8) HAMD total score, and a minimum HAMD total score of $\geq$ 10 (on the 25-item HAMD). An optional, additional patient visit was allowed within 10 days to re-check the HAMD score once a patient reached a 50% increase. The purpose of this visit was to confirm relapse in subjects who had borderline scores on rating scales.

The timeline is schematically shown in Figure 2 (next page).

Figure 2: M-2020-0034 Study Timeline



8.2. Discussion of Study Design

The goal of this protocol was to evaluate the efficacy and safety of RBX in a population of patients with MDD who had not responded to FLX therapy. There is no accepted definition of lack of response to FLX. However, it is has been shown that increasing the daily dose of FLX from 20 mg to 40 mg leads to improvement in many patients who have not initially responded [15]. On the other hand, if patients have not responded to FLX by 6 weeks, their chances of having a good response with continued FLX treatment are decreased [16]. These two findings were incorporated in the definition of FLX non-response in this protocol.

As noted, several studies of RBX in MDD have previously been conducted, including a study which demonstrated that RBX was more effective than PBO in preventing relapse of MDD in patients followed for up to one year. None of these studies, however, were conducted in patients with MDD and who failed to respond to FLX. Therefore, to allow valid conclusions about efficacy and safety of RBX in FLX non-responders, a PBO control group was necessary in this protocol.

A PBO-controlled discontinuation design was chosen because it allowed for greater statistical power than other designs (thus minimizing the number of patients exposed to PBO administration) [17]. In this design, the exposure to PBO during symptomatic depressive illness in individual subjects was also less than in other designs. On the other hand, this kind of design does not provide estimates of the magnitude of absolute treatment effects and does not strictly measure response to study drug in the target population. Preventing relapse, however, is a legitimate indicator of the drug's effect and an important clinical measure.

A washout period between the discontinuation of FLX treatment and the start of the RBX protocol was another consideration. A previous study in which RBX and FLX were administered concomitantly to healthy volunteers did not raise any safety concerns [18]. These data made it possible for the present protocol to allow a rapid switch (in 72 hours or less) from FLX to RBX, despite FLX's relatively long-half life of several days. In clinical settings, a washout period is generally not desirable because it is often not practical to maintain symptomatic patients on no treatment. Therefore the rapid switch utilized in this protocol make results more applicable to usual clinical practice.

8.3. Study Population

8.3.1. Inclusion Criteria

The protocol listed these inclusion criteria:

Patients must be non-responders to open-label FLX under the following conditions:

- Patients of either sex, of any race, ages 18-65 years
- Patients must have received open label FLX given daily for at least 6-12 weeks (at least 40 mg/day FLX must have been taken for the last 3 weeks)

- Non-response to open-label FLX is defined as: a Clinical Global Impression Improvement (CGI-I) score of 3-7 ("minimally improved" to "very much worse") for each of the last two weeks of the FLX treatment while continuing to meet Diagnostic and Statistical Manual-IV (DSM-IV) criteria for MDD without Psychotic Features (American Psychiatric Association 1994) and a HAMD-25 score of >8

At the time of entry into Part 1 patients must:

- be outpatients with MDD diagnosed with the use of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID). If the patient had been diagnosed with a complete SCID prior to FLX treatment the Mood Disorders, Mood Episodes, and Psychotic Screen modules will be repeated to confirm the MDD diagnosis (without psychotic features) within 1 week of screening.
- be evaluated using the 25-item Hamilton Rating Scale for Depression (HAMD) and Addendum at screen and on Day 1 prior to dosing with open-label RBX.
- be receiving FLX.
- provide signed, written informed consent.

8.3.2. Exclusion Criteria

The protocol listed these exclusion criteria:

- DSM-IV diagnosis of Major Depressive Episode with Psychotic Features.
- DSM-IV diagnosis of Cyclothymia Disorder.
- DSM-IV diagnosis of Bipolar I or Bipolar II Disorder
- Meeting criteria for DSM-IV diagnosis of Substance Related Disorders within the past 6 months.
- Meeting criteria for DSM-IV diagnosis of Schizophrenia or Other Psychotic Disorders.
- History of MDD associated with endocrine disorders: hypo- and hyper-thyroidism tested by TSH and T4; adrenal insufficiency, Cushing's syndrome.
- Positive pregnancy test for women of childbearing potential.
- Females who are breastfeeding.
- Refusal by female patients of potential child-bearing age to use effective contraceptives during the study period.
- Participation in any clinical study with an investigational compound in the 4 weeks preceding the study.
- History or presence of gastrointestinal, liver, or kidney disease, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.

- History of seizures or brain injury; current evidence of clinically important hematopoietic, respiratory or cardiovascular diseases. Current evidence of urinary retention, or glaucoma.
- Any important clinical illness in the 4 weeks preceding the study which might interfere with the conduct of the trial.
- Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission.
- Electroconvulsive Therapy (ECT) in the previous 6 months.
- High risk of suicide as assessed by Investigator's judgment, score $\geq$ 3 on HAMD suicide item (i.e. suicide ideas, suicide gesture or attempt at suicide), or attempted suicide during the present episode.

8.3.3. Removal of Patients from Therapy or Assessment

A patient could be withdrawn from the study treatment if, in the opinion of the Investigator, it was medically necessary or if it was the wish of the patient. Termination of test therapy prior to completion of the protocol treatment period was considered due to adverse events, clinical deterioration or switch to mania.

Patients who fail to respond to the 8-week open-label treatment with RBX (Part 1) were withdrawn from the study. Patients who experienced relapse of MDD during the post-randomization treatment (Part 2) were also withdrawn from the study.

In case of treatment discontinuation, sites were instructed by the protocol to describe the reasons for the withdrawal to subjects and, whenever possible, irrespective of the reason for withdrawal, to examine discontinued subjects as soon as possible. Relevant samples (lab tests, ECG and any diagnostic procedures which were necessary to define the event leading to withdrawal) were to be obtained and all relevant assessments completed, preferably according to the schedule for final assessment. The CRFs were to be completed as far as possible and provided to the sponsor. If a subject did not return for a scheduled visit, every effort was to be made to contact the subject. In any circumstance, subject outcome was to be carefully documented.

8.4. Treatments

8.4.1. Treatments Administered

During the protocol, subjects received RBX or RBX and PBO. The study medications were provided as scored tablets that allowed dose adjustment if necessary. PBO and RBX tablets were identical in appearance. Separate subject numbers were assigned for Part 1 and Part 2, and study drugs were packaged and labeled accordingly. The Part 1 and Part 2 numbers were linked for each subject. Part 1 supplies were packaged in bottles containing enough study medication for one week of treatment. For each subject, 8 bottles labeled with the Part 1 subject number and the indication "week 1" to "week 8" were provided. Each bottle for each

week contained the medication necessary for 1 week plus additional tablets for difficulties in scheduling visits and possible losses (total of 25 tablets), prepared according to the twice daily regimen with 1 tablet for the "morning" and 1 tablet for the "evening" dose for weeks 1, 2, 3 and 4 and 1 tablet in the morning and 1 or 1 1/2 tablet(s) in the evening for weeks 5-8 (this allowed investigators to increase the dose after week 4 if they deemed it necessary). Part 2 supplies were labeled using a different color than Part 1 supplies to clearly distinguish them. Part 2 supplies were packaged in bottles and labeled with the Part 2 subject number. For each subject treated post-randomization, 24 bottles labeled with the subject number and the indication "week 9" to "week 32" were prepared. Each bottle for each week contained the medication necessary for 1 week plus additional tablets for difficulties in scheduling visits and possible losses (total of 25 tablets), prepared according to a twice daily regimen with 1 tablet in the morning and 1 or 1 1/2 tablet in the evening for weeks 9-32.

Drug supplies were stored at room temperature. All drug supplies were handled under the direct responsibility of the investigator. Study monitors checked drug storage conditions during site visits.

8.4.2. Identity of Investigational Products

RBX and PBO supplies were manufactured and supplied by Pharmacia & Upjohn, Italy and contained either 4 mg of RBX and excipients, or excipients only in the case of PBO. The lot numbers were 28,439 for RBX, and 28,449 for PBO.

8.4.3. Method of Assigning Patients to Treatment Groups

In Part 1 all subjects received open-label RBX therapy. Responders in Part 1 were entered into the double-blind portion of the study . This was done by site investigators by consecutively assigning a coded double-blind treatment (either RBX or PBO) to each subject.

8.4.4. Selection of Doses in the Study

The 8 to 10 mg/day doses of RBX for this study were chosen based on the results of previous RBX studies in patients with MDD [19].

8.4.5. Selection and Timing of Dose for Each Patient

The timing of daily dosing was determined by the pharmacokinetic profile of RBX [19]. The half-life of RBX in subjects aged 18-65, who do not have significant hepatic or renal disease, is about 13 hours. This duration allows for twice daily dosing. This protocol excluded subjects who had significant medical illnesses that would hamper the metabolism of RBX, so for the study population, the twice daily dosing was appropriate for all subjects in this protocol.

8.4.6. Blinding

All subjects entered into Part 1 were treated with open-label RBX in an unblinded fashion. On Day 57 (end of week 8), a response determination was made for each subject. RBX nonresponders were withdrawn from the study. RBX responders were randomized into Part 2 in a double-blind fashion on Day 57 to continue RBX or begin PBO.

8.4.7. Prior and Concomitant Therapy

No concomitant psychotropic medication other than temazepam or zolpidem tartrate as a hypnotic on a p.r.n. basis (eg, temazepam 7.5-30 mg or zolpidem tartrate 5-10 mg po QHS prn during the study) was allowed. The administration of other concomitant psychotropic drug was considered a protocol deviation.

Other therapy considered necessary for the patient's welfare could be given at the discretion of the Investigator. All such therapy was to be recorded in the Case Report Form. No other investigational drug could be used concomitantly with the study drug. Patients were not allowed to participate concurrently in any other clinical drug study. Women of childbearing potential had to use an effective means of contraception while on study. Over the counter (OTC) medications were allowed on a p.r.n. basis as symptomatic treatment. They were recorded along with other medications in the non-investigational medication case report forms.

The first amendment of the protocol (dated June 19, 1999) excluded food supplements with potential central nervous system effects, such as St. John's Wort, kava, ginseng, and melatonin. This amendment also instructed investigators to exercise caution in enrolling subjects who were taking drugs that were potent inducers or inhibitors of cytochrome p450 3A4 (this isoenzyme plays a prominent role in the metabolism of RBX).

8.4.8. Treatment Compliance

Subject compliance was strictly monitored. Dosing diaries were provided to each subject for daily recording of drug administration. The investigator's staff checked for regular consumption of experimental treatment. Sites were instructed to retain diaries as source documents.

The investigator was also responsible for drug accountability and kept a record of the test compounds received from Pharmacia & Upjohn as well as of the dispensed and returned drug. Discrepancies between dispensed and returned study medication were explained and recorded.

Medication was dispensed to the subject at each visit, and the bottle(s) of the previous supply were returned.

Sites were instructed to return all unused medication and empty bottles to Pharmacia & Upjohn.

8.5. Efficacy and Safety Variables

8.5.1. Study Schedule

Table 2 documents the schedule of study activities.

Table 2: STUDY FLOW-CHART

		PART 1					PART 2		
Day*	**Screen****	**1**	**8, 15 and 22**	**29**	**36, 43 and 50**	**57[1]**	**58-113**	**141-197**	**225[1] (or end of treatment)**
Week	**Screen****	**-**	**1,2 and 3**	**4**	**5,6 and 7**	**8**	**9-16 (weekly visits)**	**20-28 (monthly visits)**	**32[1] (or final visit)**
Confirm DSM- IV MDD (by SCID)[2]	✓								
Sign consent	✓								
Medical history	✓								
DSM-IV 5-Axis Clinical Dx[3]	✓					✓			✓
MGH Antidepressant Tx Resp. Scale	✓								
Physical examination	✓								✓
Randomization						✓			
ECG - 12-lead, serum chemistry, hematology and urinalysis	✓			✓		✓			✓
Serum Pregnancy Test	✓					✓			✓
Urine drug screen	✓					✓			✓
Vital signs	✓	✓	✓	✓	✓	✓	✓	✓	✓
25-item HAMD & addendum	✓	✓	✓	✓	✓	✓	✓	✓	✓
Assess for MDD relapse							✓	✓	✓
MADRS, CGI, PGI, SF36, KSQ, SASS		✓	✓ wks 1,2	✓	✓wk 6	✓	✓wks 10,12,14,16	✓	✓
RSI		✓		✓		✓	wk 16		✓
Compliance			✓	✓	✓	✓	✓	✓	✓
Medication dispensing record		✓	✓	✓	✓	✓	✓	✓	✓
Adverse Events		✓	✓	✓	✓	✓	✓	✓	✓

Abbreviations: DSM-IV = Diagnostic and Statistical Manual of Mental Disorders; Fourth Edition, MDD = Major Depressive Disorder, HAMD = Hamilton Rating Scale for Depression, MADRS = Montgomery Asberg Depression Rating Scale, CGI=Clinical Global Impressions, PGI =Patient Global Impressions, SF36 = Medical Outcome SF36, SASS = Social Adaptation Self-evaluation Scale, KSQ = Kellner Symptom Questionnaire, RSI = Rush Sexual Inventory Scale, SCID = Structured Clincial Interview for DSM-IV Axis I Disorders, wk = week, MGH Antidepressant Tx Resp. scale = Massachusetts General Hospital Antidepressant Treatment Response Questionnaire

* Visits were to be targeted to occur ± 1 day through week 16; thereafter ± 2 days

** Screening visit must have taken place within 2 weeks prior to Day 1.

[1]For any patient who withdrew between Day 1-57, all tests and forms listed for the Day 57 visit were to be completed. For any patient who withdrew between Days 58-225, all tests and forms listed for the Day 225 visit were to be completed.

[2]The following SCID Modules were to be performed and documented in source records: A = Evaluation of Mood Episode, Dysthymic Disorder, Mood Disorder due to a GMC, and Substance-Induced Mood Disorder; B = Psychotic and Associated Symptoms; C = Psychotic Disorders; D = Mood Disorders

[3]Except for MDD (which is determined by appropriate SCID Modules), the 5-Axis clinical diagnosis could be made based on a clinical interview.

8.5.2. Efficacy Variables

The primary efficacy measure for each phase was the 25-item Hamilton Depression Rating Scale total score (HAMD). Secondary efficacy measures were Clinical Global Impression (CGI), Montgomery-Asberg Depression Rating Scale (MADRS) total score, Patient's Global Impression (PGI), individual items from other versions of the HAMD, Kellner Symptom Questionnaire (KSQ), Rush Sexual Inventory (RSI), the Medical Outcomes Study short form 36 (SF-36) scale, and the Social Adaptation Self-evaluation Scale (SASS). A clinical 5-Axis diagnosis was recorded at the start of the study, and at the end of Parts 1 and 2.

The clinical efficacy assessments are described below:

-Hamilton Depression Rating Scale [20,21,22] is the standard scale used for rating severity of depression. It is a clinician rated scale based on of results of a patient interview. The individual items on the HAMD are rated according to their severity either on a 0-2 or a 0-4 point scale. In this protocol the 25-item version was used for primary efficacy assessment and to make the determination of response at the end of Part 1, but data were collected to allow assessments based on other versions (17-item, 28-item) item scales. Appendix 7 of the protocol, attached to this study report, shows the breakdown of individual items which comprise each scale.

-Montgomery Asberg Depression Rating Scale (MADRS) [23] is a scale based on a clinical interview. Its consists of 10 items, with each item scored on a 7-point scale, graded 0-6. A score of 0 signifies absence of the symptom in question, while a score a score of 6 signifies the most extreme form. Total score ranges from 0-60.

-Clinical Global Impression (CGI) [24] consists of three parts (Severity of Illness, Global Improvement and Efficacy Index) which the clinician fills out. The Severity of Illness and Global Improvement parts are 7-point measures. The Efficacy Index calls for an estimation of therapeutic effect in relation to severity of side effects based on a 16-point scale. The Global Improvement portion and Efficacy Index refer to changes since admission to the study. For this reason, there are no values assigned to these portions at the first evaluation. The CGI scoring is similar to that found in most other scales, in that lower scores indicate better health.

-Patient Global Impression (PGI) is a single item scale in which the patient rates on a 0-10 scale the worsening, stability or improvement in his/her general condition at that time compared with the start of the study.

-Medical Outcomes Study short form 36 [25,26], also referred to as SF-36, is a general quality of life scale consisting of 36 items which compose eight subscales. Each subscale is scored separately; no composite total is calculated. General population norms exist on thousands of individuals and can be broken out for age and sex comparisons with almost any population sample. This instrument also has been used extensively in patients with clinical depression. The SF-36 is self-administered.

- The Social Adaptation Self-evaluation Scale (SASS) [27] is a 21-question self-evaluation questionnaire which explores the realm of work and leisure, relationships and patient perception of his/her ability to manage the environment. The scale was validated in a survey of the data from the general population in 4000 individuals and sensitivity to change was evaluated in a study in depressed patients comparing RBX, FLX, and PBO [26]. Answers to each item are scored from 0 to 3 (the higher the better social functioning is).

-The Kellner Symptom Questionnaire (KSQ) [28] is a 92-item, self-rated simple questionnaire which contains state scales of depression, anxiety, anger-hostility and somatic symptoms. In addition, four well-being subscales (contented, relaxed, friendly, and somatic well-being) are included. The four state scales are scored separately; a total score is also calculated. The depression cluster has shown good agreement with the Hamilton Rating Scale for Depression.

-The Rush Sexual Inventory (RSI) scale [29] is a comprehensive, succinct, self-rated patient inventory created to assess changes in sexual function over time. Each inventory consists of five visual analogue items and individual “yes/no” gender-separated items. At the first evaluation, this scale includes queries for premorbid as well as current functioning.

-For reasons of safety and as a tertiary indicator of efficacy, the "clinical" DSM-IV 5-Axis diagnosis of each subject during the trial was followed. This diagnosis was made within one week of the screening and at the end of Parts 1 and 2 (when applicable), and was based on a clinical, and not a structured, interview.

8.5.3. Safety Variables

8.5.3.1. Clinical Safety Assessments

The following clinical safety assessments were carried out. These include assessments which supplemented demographic information used to classify subjects at baseline:

1. Standard medical history at screening.
2. Standard clinical and physical examination at screening and end of study.
3. Blood pressure, pulse and oral temperature were measured with the patient rested and in the sitting position at each visit.
4. Adverse events occurring from Day 1 until the last visit were recorded. After open-label RBX treatment ended on Day 57, follow-up visits at regular intervals were performed for all patients continuing on study (i.e. for both patients continuing on RBX and for those randomized to PBO).
5. 12-lead ECG.
6. Confirm DSM-IV MDD by using the Structured Clinical Interview for DSM-IV.
7. 5-Axis DSM-IV clinical diagnosis at screening, week 8 and week 32.
8. Massachusetts General Hospital Antidepressant Treatment Response Questionnaire [30]. This self-administered questionnaire queried history of medication treatment for depression prior to participation in this study, and was part of the case report forms used in the screening visit.

8.5.3.2. Laboratory Safety Assessments

ECG and laboratory tests (which included chemistry, hematology, urinalysis, thyroid function, urine drug screen, and pregnancy test) were carried out according to the schedule in Table 2. The specific laboratory assessments are noted in Appendix 3 of the protocol, which is attached to this study report.

8.5.4. Drug Concentration Measurements

Plasma drug levels were not measured in this study.

8.6. Data Quality Assurance

The following procedures were implemented to ensure the quality of the data that were collected:

- a training meeting was held to familiarize the investigators and coordinators with the protocol and with the assessment instruments
- an Investigator's Brochure and reference manual were given to each investigative site
- data were collected on standard CRFs provided to each investigator by the sponsor
- investigators and institutions guaranteed access to source documents for quality assurance audits by Pharmacia & Upjohn personnel as well as appropriate regulatory agencies
- monitoring visits were made periodically during the study to ensure that all aspects of the protocol were being followed
- source documents were reviewed for verification of agreement with data on the patient CRFs
- all safety laboratory measurements were conducted by SmithKline Beecham Clinical Laboratories
- laboratory data entered at SmithKline Beecham were electronically transmitted to Pharmacia & Upjohn for analysis
- ECGs were evaluated by Premier Research Worldwide; data were analyzed by Pharmacia & Upjohn
- Pharmacia & Upjohn Standard Operating Procedures were followed in the conduct and analysis of the study

8.7. Statistical Methods and Determination of Sample Size

8.7.1. Determination of Sample Size

Sample size was calculated based on the assumption that at least 50% of the patients who discontinue treatment experience a relapse within 6 months compared to 20% of the patients who continue on active medication. This was based on results of a previous reboxetine study [31] and published papers [32,33,34]. At significance level of 0.05 (2-tailed), power level 0.8, the number of patients required to detect a 30% difference in relapse rate was 78 (39 per treatment arm). Assuming that 10% of the patients randomized into the double blind phase

were non-evaluable for efficacy, 87 patients were required for randomization at Day 57 of the study. It was estimated that about 200 patients were needed for the open label phase to get enough patients for randomization.

The study was terminated prematurely (see Section 9). At the time of study closure,128 patients were enrolled, and 47 patients were randomized into the blinded medication phase.

8.7.2. Data Sets Analyzed

The intent-to-treat (ITT) data set, which includes all patients who were enrolled into the trial and were given any study medication, was used for all analyses for the open label phase.

Patients who were randomized and had any post randomization evaluations were included in the analyses for the blinded medication phase.

8.7.3. Rules for Estimation of Missing Data

For the analyses of the psychometric scales in the open label phase, two types of analyses were performed: the "last observation carried forward" (LOCF) and "observed cases" (OC). The OC approach was used in the analyses for the blinded medication phase.

For LOCF analyses, if an individual component score on the questionnaires was missing at a post baseline visit, the last observed score of the component was carried forward as an estimate of the missing score. The score at screen was used as an estimate of any missing observation at baseline.

For observed cases (OC) analysis, no observation was carried forward. If an individual component score is missing, the total score was treated as missing.

8.7.4. Demographic and Baseline Characteristics

Demographic and baseline conditions (e.g. sex, age, pretreatment psychiatric condition) were summarized separately for subjects enrolled into the open label phase and subjects randomized into the blinded medication phase. Categorical variables were summarized using frequency counts and percentages, and continuous variables using means, standard deviations, and ranges. Comparability of patients randomized into the two treatment groups was assessed using t-test for continuous variables and the chi-squared test or Fisher's exact test for categorical variables.

8.7.5. Efficacy Analyses in the Open Label Phase (Part 1)

Analyses in the open label phase include summarization by visit of patients' scores on the various psychometric scales and some of their subscales and individual items. The change of the mean scores from baseline were tested for statistical significance using the paired t-test.

The following lists the items, scales and subscales analyzed:

HAMD – all 36 individual items. 25-item HAMD, 17-item HAMD, 28- item HAMD total scores.
CGI: severity of illness, global improvement, CGI efficacy index.
Patient Global Impressions.
Montgomery-Asberg Depression Rating Scale (MADRS): individual item and total score.
Kellner Symptom Questionnaire: depression, anxiety, somatic, and anger hostility susbscales.
Rush Sexual Inventory: all individual items.
SF-36 Health Survey: social functioning, physical functioning, role physical, role emotional, vitality, bodily pain, mental health and general health subscales.
Social Adaptation Self-Evaluation Scale (SASS).

The response rate to reboxetine at the end of 8 weeks of treatment was calculated using the definition of 50% reduction in HAMD-25 total scores and CGI improvement of "very much improved" and "much improved". This calculation was based on observed cases and followed the criteria the investigators used for randomizing the patients.

Further, to enable comparisons with other study results, a less restrictive and more commonly used definition of 50% reduction in HAMD scores (without the condition about the CGI improvement) was used in calculating the response rates, using the LOCF approach on all intent-to-treat patients. This calculation was performed on all three versions of HAMD, i.e. 25-item HAMD, 17-item HAMD, and 28-item HAMD.

8.7.6. Efficacy Analyses in the Blinded Medication Phase (Part 2)

Relapse rates and remission rates at the end of treatment were calculated for the two treatment groups. Relapse was defined as 50% increase or more in the 25-item HAMD total score after randomization, with a minimum score of 10. A patient was considered to be in remission if the 25 item HAMD total score was 7 or less.

The Kaplan-Meier survival function was used to estimate the time from randomization to relapse, and the log-rank test was used to test for treatment difference of the distributions. Time to relapse was calculated as the number of days between randomization and the day the patient was confirmed to have relapsed. Patients who terminated early (other than relapse) were treated as censored cases in the survival analysis.

Due to the small number of participants in most of the visits in the blinded medication phase, patients' mean scores on the questionnaires were summarized by treatment group and visit, without any statistical testing. These analyses were conducted using the observed cases approach.

8.7.7. Safety Analyses

8.7.7.1. Adverse Events

Frequencies of treatment emergent adverse events were summarized by body system and COSTART term, by maximum severity, and by gender. Treatment emergent adverse events that were considered to be related to study medication, and those that resulted in early termination of the patients, were also summarized and listed.

In addition, the following categories of adverse events were summarized by body system and COSTART term:

- adverse events that started while patients were on fluoxetine and were still present at baseline.
- adverse events that started in the first four weeks of treatment.
- adverse events that started in the fifth to eighth week of treatment.

Events that started before treatment were listed with the investigators' comments on their relatedness to fluoxetine.

Adverse events that started in the blinded medication phase were summarized and listed by treatment group.

Serious adverse events were listed.

8.7.7.2. Laboratory Tests

Summary statistics for each laboratory assay were calculated and displayed by visit in the open label phase. The mean change from baseline was summarized and tested for statistical significance using the paired t-test. Shift tables were constructed to show the changes in the frequencies of normal/abnormal findings before and at the end of treatment.

Laboratory test results were summarized by visit and treatment in the blinded medication phase.

Patients who had any post baseline abnormal laboratory results were listed.

8.7.7.3. Vital signs

Vital signs, which include weight, systolic and diastolic blood pressure, sitting pulse, temperature, and respiration rate, were summarized by visit. The paired t-test was used to determine the significance of the changes since baseline.

Patients showing clinically significant changes in vital signs during treatment were listed.

8.7.7.4. Electrocardiograms

Methods used in the analyses of ECG results were similar to those used for analyzing the laboratory results. ECG data analyzed include heart rate, PR, RR, QRS, QT intervals, and QTc intervals with Bazett and Fredericia corrections.

8.7.8. Significance Level of Hypothesis Testing

An adjusted alpha level of 0.049 was used in the final analyses, because 0.001 was spent in the interim analyses. (See Section 9:)

All analyses were performed using PC SAS Version 6.12.

9. CHANGES IN THE CONDUCT OF THE STUDY OR PLANNED ANALYSES

In March 2000, the decision was made to stop this study prior to completing enrollment of the originally planned number of patients. This decision was based on the results of a preplanned interim analysis (see protocol amendment 2, dated January 31, 2000) conducted to determine the likelihood of a significant result being found if the original number of patients were enrolled in part 1 and completed dosing in part 2 of the study. No one involved in the conduct of the study (i.e., data editing and cleaning up of the data) was unblinded in any way to these results. These included but were not exclusively the study statistician, the medical monitor, the Clinical Trial Specialist and the field staff.

The conditional analysis was performed by Kerry Barker, an independent statistician, on March 15, 2000. The blind was broken this date (only the statistician was given access to the unblinded results). The conclusions of this analysis were then sent to JR Luderer (Vice-President, US Medical Affairs, Pharmacia & Upjohn) on the same day. Only the overall response rates and the conditional powers were presented. The by-treatment response rates were not presented. The interim results, as well as the randomization codes, were then sealed and not opened until the study had been closed and data had been edited and cleaned. The results of this analysis are summarized in the following paragraphs and table.

There were a total of 22/35 (65%) patients who relapsed during the second phase of the study at the time of the interim analysis. Broken out by treatment we found 11/17 (65%) were in the reboxetine group and 11/18 (63%) received placebo. Conditional power was calculated [35] using the observed response rates (65% for reboxetine and 63% for placebo) under the original assumption that there was a true difference of 30% between reboxetine and placebo. The results under various values of reboxetine and placebo, such that their difference is 30%, are presented in Table 3. From this table we can see that the conditional power is less than 20% under any condition in which the true response rates are different by 30%. Similarly, the conditional power was only 30% when one assumed a true difference of 35%.

Table 3. Conditional Power Analysis Under the Assumption that the True Difference in Relapse Rates is 30%

True Percentage - Reboxetine	True Percentage - Placebo	Conditional Power
0.45	0.75	0.19894
0.50	0.80	0.19892
0.55	0.85	0.19849
0.60	0.90	0.19724

Examination of the data showed that the majority of the relapses were minor. Therefore, further conditional power analyses were also done using alternative definitions of relapse. The most optimistic (a definition of relapse that produced the largest positive difference between reboxetine and placebo) resulted in an observed response rate of 63% for reboxetine and 71% for placebo. Even under this new (most optimistic) definition of relapse the conditional power of detecting a 30% difference was at most 60% (and more likely 50%). Analyses were also performed without some subjects that may have been protocol violations. Again conclusions did not change.

Thus it was apparent it was unlikely that enrollment of additional patients would result in a positive outcome (ie, a difference between the two treatment groups with regard to the occurrence of relapse). The decision was made to stop enrollment in the study. Additional screening and enrollment ceased immediately after these results were reviewed and the decision was made. Patients who were ongoing in Part 1 at the time the study was discontinued were allowed to continue that part of the study but were not allowed to be randomized into Part 2. Patients who were ongoing in Part 2 were to be discontinued from study medication within 2 weeks and considered for enrollment in an open-label continuation protocol. The study blind for Part 2 was not broken for these patients.

10. RESULTS

10.1. Study Patients

10.1.1. Disposition of Patients

Table 4 summarizes the disposition of the 128 patients participating in this study.

Table 4. Disposition of Patients Participating in Protocol 034

Part 1 (Open label)		Part 2 (Double blind)		
Number of Patients	**Reboxetine**	**Number of Patients**	**Reboxetine**	**Placebo**
Enrolled	128	Randomized	24	22
Completed 8 weeks	79	Completed blinded phase (ie, week 32) without relapse	0	2
Discontinued during 8 week treatment	49	Relapsed before week 32	13	13
Discontinued because of adverse events	17	Discontinued due to study closure	7	4
Discontinued because of lack of efficacy	12	Discontinued for other reasons	4	3
Discontinued for other reasons	20			
Source: Tables DS3, DS4 and EFF1				

Part 1 - A total of 128 patients were enrolled in Part 1 of this study by the 28 psychiatric centers with expertise in clinical trial methodology (Table DS1). Seventy nine patients (79; 61.7%) completed eight weeks of treatment; forty nine (49) patients discontinued before 8 weeks of treatment (Table DS3). The most common reasons for discontinuing treatment were an adverse event (17 patients) or a failure to respond to the reboxetine treatment (12 patients).

Part 2 - Of the 79 patients who completed Part 1 of the study, 47 were randomized into the double blind part of the study (Part 2). Twenty of the 28 centers randomized patients into Part 2. Three patients (all in the placebo group; numbers 101044, 151038 and 131125) were randomized by error into Part 2. These patients failed to respond adequately to reboxetine in Part 1 (ie, did not achive a >50% decrease in their HAM-D total) but received doses in Part 2 and thus were included in the analyses. One of the 47 (patient 91097) did not have any follow-up data and was excluded from the Part 2 analyses (Table DS2); thus, 46 were included (reboxetine = 24; placebo = 22).

Forty four of the 46 patients (reboxetine = 24; placebo = 20) discontinued before the end of the study. Most of these were due to lack of continued efficacy of the study drug (ie, relapse; reboxetine = 13; placebo = 13; Tables DS4 and EFF1). Most of the other patients who discontinued in Part 2 did so because the study was cancelled. Lastly, two additional patients (numbers 11160 and 11167) were eligible for randomization but were not randomized because of the study closure (see Section 9).

Only two patients (numbers 31020 and 151037) completed the 32 weeks of the study, ie, both Parts 1 and 2. Table DS5 provides a listing of the disposition of the 126 patients who discontinued from this study regardless of whether they discontinued in Part 1 or Part 2. Table DS6 documents the number of patients remaining in the study for each week.

10.1.2. Protocol Deviations

Table 5 documents the 15 patients with protocol violations/deviations occurring during the course of this study. Except as noted for patient 241032, the data from these patients were included in the analyses presented herein.

10.1.3. Data Sets Analyzed

All patients who were enrolled in Part 1 of the study, who received at least one dose of study drug were included in the data set which was analyzed. Thus, all "intent-to-treat" patients were included. As previously noted, one patient who was randomized in Part 2 did not have any follow-up data and was excluded from Part 2 analyses.

Table 5. Patients with Protocol Violations/Deviations During Study

Violation Category	Patient Number	Description
Inclusion/Exclusion criteria	91036	MDD diagnosis not confirmed at screen, nor before patient's early termination from the study
	101044	Complete SCID not done prior to reboxetine treatment. SCID at screen was done confirming MDD
	111057	Past MDD was omitted from SCID
Drug screen failure	81052	Opiates at screen – took Vicodin x3 for low back pain
	111057	Opiates at screen, tested negative at repeat urine test.
	201068	Had elevated AST and ALT at screen. Was followed weekly after study.
Concomitant medication	41094	Took alprazolam for 2 days in week 2. Patient continued onto part 2.
	211147	Took venlafaxine and hydroxyzine for depression and anxiety a few days prior to early termination.
	241031	Took fluoxetine for depression a few days before early termination.
	201092	Took bupropion and sertaline for depression before early termination.
Wrongly randomized by study sites	101044	Wrongly randomized with less than 50% reduction in HAMD score at end of week 8. Also terminated early due to prohibited therapy.
	151038	Patient was inadvertently randomized. Less than 50% reduction in HAMD at the end of week 8.
	131125	Patient was wrongly randomized due to miscalculation of HAMD score.
Relapse criteria	81103	Less than 50% increase in HAMD score (increased from 10 to 14) in randomization phase, yet investigator considered patient relapsed.
Assessment after treatment termination	241032	Patient was assessed 3 months after dropping out . This last assessement was not included in the statistical analysis.

10.1.4. Demographic and Other Baseline Characteristics

10.1.4.1. Demographic Characteristics

Part 1 - Tables DM1 and DM2 document the demographic characteristics of the 128 patients enrolled in Part 1 of the study. As expected, approximately 2/3 of the population were females (Table DM1). The majority of patients were caucasian, were currently married and had at least a high school education. Patients were about equally divided with regard to living with a spouse or living alone. About 2/3 of the subjects were employed either full- or part-time. The mean age of the patients was 44 years (Table DM2).

Part 2 – The demographic characteristics of the 46 patients randomized in Part 2 (24 in the reboxetine group and 22 in the placebo group) are documented in Tables DMM1 and DMM2. There were numerically fewer females (reboxetine = 54.2%; placebo = 72.5%; p=0.233), more caucasians (reboxetine = 95.8%; placebo = 86.4%; p=0.101) and more married subjects (reboxetine = 54.2%; placebo = 40.9%; p=0.752) in the reboxetine group than in the placebo group. The two groups were essentially identical with regard to age, weight and height.

10.1.4.2. Medical History and Physical Examination Findings

Part 1 - Tables DM3 and DM4 summarize the results of the medical histories and physical examination findings from the 128 patients. The majority of the patients had at least one positive finding on their history (Table DM3). Some patients (0.8-16.4% depending on the body system) had a current positive finding on their physical examination (Table DM4); however, these did not interfere with their participation in the study.

Part 2 - Tables DMM3 and DMM4 summarize the results of the medical histories and physical examination findings from the 64 patients. Between one-third and one-half of the patients had a positive finding on their history (DMM3). There were no appreciable differences between the two treatment groups with regard to histories or physical examinations.

10.1.4.3. Psychiatric History

Part 1 - The psychiatric history of the patients who were enrolled in this study is summarized in Tables DM5 through DM14 and DM18. Briefly, the patients had undergone multiple episodes of depression (mean 8.3); the current episode had been ongoing for approximately 4.5 years at the time they were enrolled in the study (Table DM8). About 17% of the population had previously been hospitalized for treatment of their depression (Table DM5). About half the patients were of the melancholic subtype (Table DM11) with extreme mood reactivity (Table DM14). The mean score on the Hamilton Rating Scale (25-item version) at the screening visit was 29.3 (range 15-48; Table DM18).

Part 2 – Table 6 summarizes those aspects of the psychiatric history where there was an appreciable difference between the reboxetine and placebo groups. There seemed to be no

differences in the other variables (see Tables DMM5 through DMM 17). The mean Hamilton Depression score at baseline was 27.3 in the reboxetine group and 26.4 in the placebo group (Table DMM18).

There were no significant differences between the two groups, at least in part due to the small number of patients in the two groups. More patients in the reboxetine group had been treated with psychiatric medication, had previously been treated with benzodiazepines and had received mood stabilizers than those in the placebo group. Further, patients in the reboxetine group reported their first episode of Major Depression at an earlier age (mean = 25.1 vs 32.7 for placebo; p=0.082) and had had more episodes than those in the placebo group (10.8 vs 3.6; p=0.215). Additionally, their current episode was longer than that for patients in the placebo group (mean = 6.1 months vs 2.4 months; p=0.141. Collectively, these differences suggest that the patients in the reboxetine group may have been more chronically ill than those in the placebo group.

Table 6. Psychiatric History Variables with an Apparent Difference Between Treatment Groups in Part 2

Variable	Reboxetine	Placebo
Number of patients	24	22
History of treatment with psychiatric medication	50.0%	9.1%
History of treatment with benzodiazepines	29.2%	4.5%
History of treatment with mood stabilizers including lithium	12.5%	4.5%
Mean age of onset of first episode of Major Depression	25.1	32.7
Mean number of episodes of Major Depression	10.8	3.6
Mean duration of last episode of Major Depression (months)	4.7	3.0
Mean duration of present episode of Major Depression (months)	6.1	2.4
Diagnosis of melancholic subtype	45.8%	36.4%
Precipitating stress absent in current episode	50.0%	22.7%
Source: Tables DMM5, DMM6, DMM8, DMM9 and DMM11		

10.1.4.4. Previous Treatment for Depression

Part 1 - Previous treatment with psychotropic drugs prior to entry into the study is summarized in Tables DM15, DM16 and DM17. About 75% of the patients thought that previous treatment with fluoxetine was the medication that had helped them the most. However, only five patients thought that they had improved 50% or more on this treatment.

10.1.5. Concomitant Medications

The concomitant medications taken by patients in this study are documented in Tables CM1 (medications taken prior to the time of study entry), CM2 (medications taken during the open-label treatment with reboxetine [Part 1]) and CM3 (medications taken during double-blind treatment [Part 2]). The most common medications taken during all three-study phases

were over-the-counter anti-inflammatory/analgesics (eg, ibuprofen, acetaminophen). Collectively, these groups were reported 52 times prior to the time of study entry, 160 times in Part 1 and 31 times in Part 2 (13 times in the reboxetine group; 18 times in the placebo group).

10.2. Dosage Information

10.2.1. Extent of Exposure

Part 1 - All patients in Part 1 were treated with reboxetine on an open-label basis. The initial dose was 4 mg BID (ie, 8 mg per day). Patients doing well on this dose were continued at the same dose for the remainder of Part 1 (through week 8). After 4 weeks of treatment, the investigator could increase the dose by adding an additional 2 mg to the evening dose (ie, total daily dose of 10 mg per day). This was done for patients who had little or no improvement in their depressive symptoms and with no significant difficulty in tolerating the starting dose. Patients who had their dosage increased remained at the higher dose for the rest of Part 1; patients who could not tolerate the higher dose could resume the 8 mg/day regimen. Approximately two-thirds to three-fourths of the patients received the increased dose (ie, 10 mg/day) during weeks 5, 6, 7 and 8 (Table SM1).

Part 2 – Responder patients were randomized at the end of eight weeks of treatment; patients were randomized to either reboxetine or matching placebo tablets. Patients received the same number of tablets as they had been receiving during the last four weeks of Part 1 (ie, 8 or 10 mg of reboxetine/day or 1 placebo tablet BID or 1 placebo tablet in the AM and 1 ½ tablets in the PM). No dosage increases were allowed in Part 2; however, patients who had had their dosage increased in Part 1 could have it reduced to 8 mg/day (1 tablet BID) if they were unable to continue tolerating the higher dose. Treatment of patients was to continue through week 32 or until relapse had occurred (see Section 8.1 for definition). Again, about two-thirds to three-fourths of the patients received the 10 mg/day dose during weeks 9 through 32 of the study (Table SM2).

10.2.2. Measurements of Treatment Compliance

Patient compliance was monitored through the use of a subject-dosing diary and the return of the diary and medication bottles at each visit. The investigator kept a record of the medication dispensed and returned; discrepancies were to be recorded and explained.

10.3. Efficacy Results

10.3.1. Primary Efficacy Variable

Part 1 – The purpose of Part 1 was to select patients who responded to open-label reboxetine for randomization into Part 2 of the study. As previously noted, a responder was defined for purposes of this study as at least 50% decrease in HAMD score compared to Day 1 and CGI improvement of 1 or 2 at the end of the 8 week open label phase. Of the 128 patients who

were enrolled in Part 1, 79 completed the 8 weeks of treatment. Of the 79 completers, 57 patients (44.5% of those enrolled; 72.2% of completers) met the definition of a responder, compared to 22 completers who did not (Table EF1).

Part 2 – The primary objective of Part 2 (day 57 through week 32) was to compare the safety and efficacy of RBX vs. PBO in reducing the rate of relapse in patients suffering from a MDD resistant to FLX treatment but responsive to open-label RBX. Tables EFF1 through EFF3 document these results. Patients began to relapse shortly after randomization; patients relapsed in (ie, dropped from) the placebo group as early as week 9 and in the reboxetine group as early as week 10. Only two patients (both in the placebo group) completed 32 weeks of treatment. However, several patients (7 in the reboxetine group and 4 in the placebo group) remained under treatment at the time the study was closed.

Table EFF2 documents the survival time (ie, time remaining in remission) for patients in Part 2. The mean time for patients in the reboxetine group was 29.7 days (median = 34 days); that for the placebo group was 37.2 days (median = 35 days). There was no significant difference between the reboxetine and placebo groups (log rank test p value=0.490). The Kaplan-Meier Survival Curve is included in Table EFF2.

10.3.2. Secondary Efficacy Variables

Ten psychometric scales were used to measure efficacy in this study. These were:

1, 2 and 3. Hamilton Depression Rating Scale (HAM-D; 17-, 25- and 28-item versions)

4. Montgomery Asberg Depression Rating Scale (MADRS)

5. Clinical Global Impressions (CGI)

6. Kellner Symptom Questionnaire (KSQ)

7. Patient's Global Impressions (PGI)

8. Social Adaptation Self-evaluation Scale (SASS)

9. Medical Outcomes Study SF36 (SF36)

10. Rush Sexual Inventory Scale (RSI)

Part 1 - The Hamilton Rating Scale was the primary rating scale selected to measure efficacy in this study. As described in the Methods, three versions of the scale were used. The items (symptoms) included in each of the 3 versions are summarized in Table 7.

Table 7. COMPARISON OF ITEMS CONTAINED IN VARIOUS VERSIONS OF HAMILTON DEPRESSION (HAM-D) RATING SCALE

Item (Symptom)	17-ITEM [20]	25-ITEM [21]	28-ITEM [22]	Item (Symptom)	17-ITEM [20]	25-ITEM [21]	28-ITEM [22]
Depressed mood	x	x	x	Insight	x	x	x
Distinct quality of mood		x		Diurnal variation		x	x
Lack of reactivity		x		Weight gain		x	x
Feelings of guilt	x	x	x	Worthlessness		x	
Suicide	x	x	x	Helplessness		x	
Early insomnia	x	x	x	Hopelessness		x	
Middle insomnia	x	x	x	Loss of energy		x	
Late insomnia	x	x	x	Loss of interest		x	
Work and activities	x	x	x	Loss of libido	x	x	x
Retardation	x	x	x	Depersonalization/derealization			x
Agitation	x	x	x	Paranoid symptoms			x
Psychic anxiety	x	x	x	Obsessive/compulsive			x
Somatic anxiety	x	x	x	Hypersomnia – early bedtime			x
Gastrointestinal somatic symptoms	x		x	Hypersomnia – oversleeping			x
General somatic symptoms	x		x	Hypersomnia – napping			x
Hypochondriasis	x	x	x	Increased appetite			x
Weight loss	x	x	x	Retardation - psychic			x
Loss of appetite		x		Retardation – motonic			x

Tables EF 2 through EF13 summarize the results of the analyses of the Hamilton Depression Scale from Part 1 of the study. Both last-observation-carried-forward (LOCF) and observed-case analyses were completed. Statistics were based on change from baseline. Table 8 summarizes the results of both types of analyses of the scale totals. Only the baseline, week 1, week 4 and week 8 results are presented in Table 5. Complete results of the LOCF and observed-case analyses are presented in Tables EF6 through EF9. However, the results in Table 7 are representative of the study as a whole for both LOCF and observed-case. As can be seen, there was a significant progressive decrease in the Hamilton scores at all time periods, regardless of which version of the scale was used.

Table 8. Summary of Results of Hamilton Depression Scale (HAMD) Scores in Part 1 of Study

HAMD Version /Statistic		Baseline	Week 1	Week 4	Week 8
LOCF Analyses					
17-Item	**Mean**	17.8	16.6	13.3	11.5
	p-Value*	-----	0.007	<0.001	<0.001
25-Item	**Mean**	28.4	25.1	19.7	17.1
	p-Value*	-----	<0.001	<0.001	<0.001
28-Item	**Mean**	23.9	18.3	16.8	14.7
	p-Value*	-----	<0.001	<0.001	<0.001
OC Analyses					
17-Item	**Mean**	17.8	16.6	12.1	8.5
	p-Value*	-----	0.005	<0.001	<0.001
25-Item	**Mean**	28.4	25.0	17.8	12.1
	p-Value*	-----	<0.001	<0.001	<0.001
28-Item	**Mean**	23.9	21.0	15.4	10.8
	p-Value*	-----	<0.001	<0.001	<0.001

- P-Values are significance relative to baseline evaluation

Source: Tables EF6, EF7, EF8 and EF9

Table 8 summarizes the results of the LOCF analyses of the individual Hamilton Scale items. Only the week 1, week 4 and week 8 results are presented in Table 9. Complete results of the LOCF analyses as well as the observed-case analyses are presented in Tables EF2 through EF5. As can be seen, an appreciable numbers of items already show significant improvement at week 1. Additional improvement is seen at weeks 4 and 8.

Table 9. p-VALUES* FROM HAMILTON DEPRESSION SCALE ITEM LOCF ANALYSES WEEKS 1, 4 AND 8

Item (Symptom)	Week 1	Week 4	Week 8	Item (Symptom)	Week 1	Week 4	Week 8
Depressed mood	<0.001	<0.001	<0.001	Insight	0.707	0.033	0.058
Distinct quality of mood	0.026	<0.001	<0.001	Diurnal variation	<0.001	<0.001	<0.001
Lack of reactivity	0.096	<0.001	<0.001	Weight gain	<0.001	<0.001	<0.001
Feelings of guilt	0.319	<0.001	<0.001	Worthlessness	0.003	<0.001	<0.001
Suicide	0.018	<0.001	<0.001	Helplessness	<0.001	<0.001	<0.001
Early insomnia	0.648	0.003	0.059	Hopelessness	<0.001	<0.001	<0.001
Middle insomnia	0.024	0.183	<0.001	Loss of energy	<0.001	<0.001	<0.001
Late insomnia	0.785	0.592	0.029	Loss of interest	<0.001	<0.001	<0.001
Work and activities	<0.001	<0.001	<0.001	Loss of libido	0.001	<0.001	<0.001
Retardation	<0.001	<0.001	<0.001	Depersonalization/derealization	0.045	0.032	0.006
Agitation	0.519	0.056	0.063	Paranoid symptoms	0.095	0.034	0.033
Psychic anxiety	0.426	0.013	<0.001	Obsessive/compulsive	0.049	0.195	0.103
Somatic anxiety	0.263	0.009	<0.001	Hypersomnia – early bedtime	0.555	<0.001	<0.001
Gastrointestinal somatic symptoms	0.368	0.007	0.013	Hypersomnia – oversleeping	0.038	<0.001	<0.001
General somatic symptoms	0.387	<0.001	<0.001	Hypersomnia – napping	0.510	0.020	<0.001
Hypochondriasis	0.109	0.013	0.002	Increased appetite	<0.001	0.021	0.037
Weight loss	<0.001	0.899	0.312	Retardation - psychic	<0.001	<0.001	<0.001
Loss of appetite	0.123	0.004	0.024	Retardation – motoric	0.004	<0.001	<0.001

* p-Values are significance relative to baseline evaluation
Source: Table EF3

Additional analyses were done to evaluate the rate of response during the eight week open-label period (see Table 10). A responder was defined as any patient with a ≥50% decrease in the HAMD score. The results varied only slightly depending upon the version of the HAMD that was tested. About 5% of the patients responded by the end of the first week of treatment, increasing to about 30% at the end of the first month and then to about 50% at the end of the eight weeks (see Table EF45 for the results at the end of each week).

Table 10. Response Rate by Visit – Part 1

HAMD Version	Week 1		Week 4		Week 8	
	n	%*	n	%*	N	%*
25-item	6	4.7	38	29.7	67	52.3
17-item	6	4.7	34	26.6	58	45.3
28-item	7	5.5	36	28.1	56	45.8
* % based on the total number of enrolled patients [128] ***Source: Table EF45***						

Table EF46 documents the reason for dropout for those patients who were responders but nevertheless discontinued before eight weeks.

Table 11 summarizes the results of the analyses of the Montgomery Asberg Depression Rating scale (MADRS), the other major efficacy rating scale used in this study. Again statistics are based on change from baseline and the results of both the LOCF and observed-case analyses are presented. As can be seen, the results closely parallel those from the Hamilton Depression scale, ie, a significant progressive decrease in the score occurred in both analyses. Complete LOCF and observed case results are provided in Tables EF 26 through EF29.

Analyses of individual MADRS items are also included in Tables EF26 through EF29. Most of the individual items showed a significant decrease at weeks 1, 2 and 4.

Table 11. Summary of Montgomery Asberg Depression Rating Scale Analyses

Statistic	Baseline	Week 1	Week 4	Week 8
LOCF Analyses				
Total (mean)	26.2	23.2	17.9	15.9
p-Value*	-----	<0.001	<0.001	<0.001
OC Analyses				
Total (mean)	26.2	23.2	16.3	15.4
p-Value*	-----	<0.001	<0.001	<0.001
* p-Values are significance relative to baseline evaluation *Source: Tables EF26, EF27, EF28 and EF29*				

Table 12 provides an overview of the results from the remaining psychometric rating scales. Only selected LOCF results from baseline and Week 1, 4 and 8 evaluations are provided in

Table 12; complete LOCF and observed-case results are documented in Tables EF14 through 25 as well as EF30 and EF 31.Overall, these results are consistent with those reported for the Hamilton Depression and Montgomery Asberg scales. Both the clinician's and patient's global impressions showed a significant progressive therapeutic effect over the eight week study period. The Kellner Symptom Questionnaire not only showed a significant therapeutic effect in the depression subscale but also in the anxiety, somatic and anger-hostility subscales.

Table 12. Summary of Results of LOCF Analyses from Other Rating Scales

Scale/Statistic	Baseline	Week 1	Week 4	Week 8
Clinical Global Impressions - % patients much/very much improved	-----	5.9%	37.5%	54.7%
Clinical Global Impressions Efficacy Index – Mean*/p-Value**	-----	0.84	1.27	1.54
	-----	-----	<0.001	<0.001
Kellner Symptom Questionnaire - Depression Subscale - Mean Total/p-Value**	16.3	13.2	11.6	10.6
	-----	<0.001	<0.001	<0.001
Patient's Global Impressions - % patients much/very much better ***/p-Value**	5.2	5.3	5.9	6.0
	-----	0.480	0.007	0.003

* 16 point scale from 1 = marked clinical improvement with no side effects through 16 = worse clinical condition and side effects that outweigh the therapeutic effect; transformed scores range from 1 to 4
** p-Values are significance relative to baseline evaluation
*** 10 unit Visual Analog Scale from 0 = as much worse as one can imagine through 10 = as much improvement as one can imagine
Source: Tables EF16, EF18, EF19, EF22, EF23, EF30 and EF31

The Rush Sexual Inventory is scored on an individual-item basis, ie, no clusters or total scores are analyzed. Tables EF34 through EF44 report the results of these items from Part 1 of the study. Frequency of pleasurable thoughts, the ability to become sexually excited, the frequency of desire to initiate sexual activity, the frequency of actually initiating activity and

the overall degree of sexual satisfaction all attained significant improvement over the eight weeks of Part 1 (Tables EF36 and EF38). Sexual activities (masturbation and intercourse) increased in frequency (Tables EF39 and EF40). There were no major changes in the frequency of responses to the gender-specific yes/no questions (Tables EF41 through EF44) in either males or females.

Table 13 summarizes the results of the 8 subscales from the Medical Outcomes Study (SF36) and the total score of the Social Adaptation Self-evaluation Scale (SASS) which are measures of quality of life. Only the LOCF analyses are summarized in Table 12. Detailed results for the remainder of the LOCF analyses and all the OC analyses are provided in Tables QOL001 through QOL027. As can be seen, the SASS score as well as several of the SF36 subscales (especially those involving mental, emotional and social functioning) demonstrated significantly better function at all follow-ups than at baseline.

Table 13. Summary of LOCF Analyses of the SF36 and SASS Instruments

Scale	Baseline (Mean)	Follow-up Evaluations Mean (p-Value vs Baseline)		
		Week 1	Week 4	Week 8
SASS Total Score	29.0	31.2 (<0.001)	32.4 (<0.001)	33.7 (<0.001)
SF36 Physical Functioning	73.1	76.0 (0.033)	77.3 (0.006)	76.1 (0.106)
SF36 Role Physical	66.7	70.9 (0.111)	70.5 (0.237)	69.3 (0.435)
SF36 Bodily Pain	55.9	56.7 (0.644)	55.9 (>0.999)	54.5 (0.439)
SF36 General Health	58.0	59.6 (0.121)	61.3 (0.026)	60.8 (0.072)
SF36 Vitality	19.7	29.9 (<0.001)	38.9 (<0.001)	40.1 (<0.001)
SF36 Mental Health	38.8	45.2 (<0.001)	51.2 (<0.001)	52.0 (<0.001)
SF36 Social Functioning	40.3	47.6 (0.001)	56.2 (<0.001)	59.6 (<0.001)
SF36 Role Emotional)	20.1	29.4 (0.005)	47.1 (<0.001)	54.4 (<0.001)

Source: Tables QOL 011 through QOL018

Part 2 – Table EFF3 documents the number of patients who remained in remission (ie, their 25-Item Hamilton Depression Rating Scale Score was 7 or less) at their final evaluation. Nine of these were in the reboxetine group (37.5%) and 3 (13.6%) in the placebo group. In interpreting these numbers, one should keep in mind that only 2 of these 12 patients (both in the placebo group) completed 32 weeks of the study. The remainder discontinued early because of closure of the study.

Tables EFF4 through EFF15 record the Hamilton Depression Rating Scale scores (17- and 25-Item versions), Clinical Global Impressions, Clinical Global Impressions Efficacy Index, Patient Global Impressions, Montgomery Asberg Depression Rating Scale score, and Kellner Symptom Questionnaire clusters for Day 57 and weeks 9 through 32. Only the observed-case data are presented. Interpretation is difficult because of the changing numbers of patients at the various weeks. Patients began to relapse in (ie, drop from) the placebo group as early as week 9 and in the reboxetine group as early as week 10.

Tables EFF17 through EFF20 report the results from the Rush Sexual Inventory during Part 2 of the study. Because of the small number of patients, these results are difficult to compare in the reboxetine and placebo groups. However, no major differences in response were observed.

Tables QOL001 through QOL009 and QOL019 through QOL027 provide the Part 2 results for the SASS and SF36 scales. Both LOCF and OC analyses were done for the Part 2. There were no differences between the RBX and PBO groups on any quality of life measure. It should be noted, however, that the final scores are still better at the final follow-up than at the time of study entry.

10.3.3. Efficacy Conclusions

The results from Part 1 of this study clearly demonstrate that reboxetine is effective in treating Major Depressive Disorder in patients that have previously failed to respond to fluoxetine therapy. Approximately half of the patients enrolled in this study experienced at least a 50% decrease in their Hamilton Depression Rating Scale score at the end of eight weeks of treatment with reboxetine on an open-label basis. Both the LOCF and OC analyses of the HAMD total scores showed a consistent significant decrease from baseline throughout the eight week treatment period. An appreciable number of individual Hamilton items (ie, symptoms) already showed significant improvement at week 1. This included depressed mood, distinct quality of mood, work and activities, retardation, weight loss, helplessness, hopelessness, loss of energy, loss of interest, loss of libido, depersonalization/ derealization, increased appetite and psychic retardation. Additional improvement was seen at weeks 4 and 8.

The results from the Montgomery Asberg Depression Rating Scale closely paralleled those of the Hamilton Depression scale, ie, a significant progressive decrease in the score occurred over time in both the LOCF and OC analyses. Overall, the results of the remaining psychometric rating scales were consistent with those reported for the Hamilton Depression and Montgomery Asberg scales. Both the clinician's and patient's global impressions showed a significant progressive therapeutic effect over the eight week study period as did the Kellner Symptom Questionnaire. Sexual activity, as measured by the Rush Sexual Inventory, appeared to improve. Collectively, these data support the conclusion that reboxetine was effective in treating the depression in fluoxetine failures during the eight week study period.

For reasons that are not clear, the double blind portion (Part 2) of the study failed to demonstrate a difference between reboxetine and placebo in terms of the rate of relapse during weeks 9 through 32 of the study. Relapse in the two treatment groups occurred at the same rate. There was a suggestion that the two subgroups may have differed in several aspects of their psychiatric history that at least in part explained why these results occurred.

10.4. Safety Results

10.4.1. Adverse Events

10.4.1.1. Brief Summary of Adverse Events

Table 14 provides an overall summary of the Treatment Emergent Symptoms (TES) reported during this study. In Part 1, most of the patients reported at least one event and most of these were judged to be related to the study drug; however, one should keep in mind that this part of the study was open label. Three serious events were reported during the open label phase (see Section 10.4.2.2). Lastly, 21 patients (16.4%) discontinued the study drug during Part 1 because of adverse events.

During Part 2, 19 patients (79.2%) of the reboxetine group and 15 patients (68.2%) of the placebo group reported at least one event. A serious event was reported for one patient in each treatment group.

Table 14. Overall Summary of Treatment Emergent Symptoms (TES)

	Part 1 (Open label)		Part 2 (Double blind)			
	Reboxetine		Reboxetine		Placebo	
	n	%	n	%	n	%
Number of patients	128	-----	24	-----	22	-----
Patients with at least 1 TES	125	97.7	19	79.2	15	68.2
Serious	3	2.3	1	4.2	1	4.5
Patients who discontinued due to adverse events	21	16.4	1	4.2	0	0
Source: Tables AE5, AE7, AE8, AE16, AE16 *Information on drug-related adverse events in Part 1 are presented in appendix Tables AE7,AE9, AE16a.*						

10.4.1.2. Events

Part 1 – Table 15 reports the most frequently occurring events (ie, events reported by >2.5% of patients) that were reported before study drug treatment was initiated previous protocol events prior to Day 1 aren't AE's unless they worsen after Day 1 by definition. Those are not treatment emergent in Part 1. At least one event was reported by 55 patients (43.0%). Table AE1 reports events by body system, Table AE2 lists reports by COSTART term and Table AE3 provides a patient listing of all events. A total of 55 patients reported at least one event; 99 different events were reported. As expected, the most common events were symptoms that occur as part of Major Depressive Disorder.

Table 15. Most Common Events (>2.5% of Patients Reporting) Occurring Before Start of Treatment in Part 1

Adverse Event	Number of Patients Reporting (%)
Number of patients reporting at least 1 adverse event	55 (43.0%)
Headache	5 (3.9%)
Fatigue	4 (3.1%)
Dry mouth	9 (7.0%)
Insomnia	7 (5.5%)
Decreased libido	7 (5.5%)
Somnolence	8 (6.3%)
Sexual dysfunction	4 (3.1%)
Source: Table AE2	

Table 16 summarizes the most frequent (ie, >5% of the patients) adverse events reported during the eight weeks of Part 1. Table AE4 reports the frequencies of reports by study period, AE5 summarizes the frequency by body system, AE6 lists the events by COSTART term, AE7 lists the frequency of those events considered to be related to study medication by COSTART term and AE9 provides a patient listing of events related to study medication.

As can be seen from Table 16 most of the events reported again are symptoms usually associated with the occurrence of Major Depressive Disorder. Further, several of them occurred, albeit at a lower occurrence, prior to the time study medication was started (see Table 15).

The frequencies of adverse events by maximum severity are listed in Table AE11. As can be seen, most of the reports are mild or moderate in severity. A total of 53.9% of the patients reported an event of mild intensity and 29.7% reported an event of moderate intensity.

Tables AE13 and AE14 report the occurrence of events by their time of onset (within four weeks of the start of treatment vs after four weeks. Most of the events started within the first four weeks. A total of 124 patients (96.9%) reported events within the first four weeks compared to 73 patients (57.0%) in the last four weeks.

Table 16 illustrates the early onset of the five most commonly occurring adverse events. As can be seen in each case the events most often occurred during weeks 1 through 4 and then sharply decreased during the last four weeks.

Table 16. Most Commonly Reported Adverse Events – Percentage Of Patients Reporting by Onset Time

Adverse Event	Event First Reported			
	Before Baseline	Total (Weeks 1–8)	During Weeks 1 - 4	During Weeks 5 - 8
Insomnia	5.5	47.7	41.4	6.3
Headache	3.9	47.7	40.6	17.2
Dry mouth	7.0	43.8	39.8	6.3
Constipation	0.8	28.1	24.2	5.5
Diaphoresis	2.3	26.6	24.2	3.9
Source: Tables AE2, AE13 and AE14				

Lastly, Table AE12 summarizes the frequency of adverse events in Part 1 by patient gender. Overall, 97.6% of males and 97.7% of females reported events. The vast majority of events occurred in equal frequency in males compared to females. Although the number of patients reporting are small, the number reporting headache, upper respiratory infection, vasodilation, dry mouth, dizziness and nervousness occurred more often in females than in males and impaired urination occurred more often in males than in females.

Part 2 – Tables AE15 and AE16 summarize those events that started during the blinded phase of the study (ie, Part 2). More patients in the reboxetine group (79.2%) reported at least one event compared to the placebo group (68.2%). Most of these occurred in the body (62.5 vs 54.5%) and nervous (37.5 vs 22.7%) systems. However, there were no specific symptoms that seemed to occur more often in the reboxetine group. Table 17a summarizes the most frequent adverse events (>5% of the patients in any treatment group) reported in the blinded phase. Table AE16a provides a patient listing of events occurring during Part 2 of the study.

Post-Study Follow-up – Table AE18 provides a listing of those events requiring follow-up after completion of Part 2. Also included are follow-ups needed from those patients who discontinued in Part 1. In all cases, the event either resolved or became chronic except for those cases that were unknown because the patients were lost to follow-up.

Table 17. Number of Patients (>5% of Patients) Reporting Adverse Events by COSTART Term in Part 1

Body System/COSTART Term	Number of Patients Reporting Event (%)	Event Considered to be Related to Study Medication (n [%])
Body		
Abdominal cramp	7 (5.5%)	<5%
Abdominal distension	7 (5.5%)	<5%
Back pain	16 (12.5%)	<5%
Chills	18 (14.1%)	14 (10.9%)
Fatigue	7 (5.5%)	<5%
Flu syndrome	7 (5.5%)	<5%
Headache	61 (47.7%)	43 (33.6%)
Localized pain	12 (9.4%)	<5%
Upper respiratory infection	17 (13.3%)	<5%
Cardiovascular		
Palpitation	8 (6.3%)	7 (5.5%)
Vasodilation	20 (15.6%)	18 (14.1%)
Digestive		
Decreased appetite	15 (11.7%)	15 (11.7%)
Constipation	36 (28.1%)	33 (25.8%)
Diarrhea	8 (6.3%)	<5%
Dry mouth	56 (43.8%)	56 (43.8%)
Dyspepsia	19 (14.8%)	12 (9.4%)
Nausea	26 (20.3%)	21 (16.4%)
Nervous		
Anxiety	14 (10.9%)	12 (9.4%)
Dizziness	32 (25.0%)	28 (21.9%)
Insomnia	61 (47.7%)	50 (31.9%)
Nervousness	13 (10.2%)	11 (8.6%)
Paresthesia	11 (8.6%)	9 (7.0%)
Somnolence	14 (10.9%)	12 (9.4%)
Skin		
Diaphoresis	34 (26.6%)	30 (23.4%)
Respiratory		
Rhinitis	7 (5.5%	2 (1.6%)
Sinusitis	8 (6.3%)	0 (0.0%)
Special Senses		
Taste perversion	8 (6.3%)	8 (6.3%)
Urogenital		
Abnormal ejaculation	9 (7.0%)	9 (7.0%)
Impotence	7 (5.5%)	<5%
Impaired urination	17 (13.3%)	14 (10.9%)
Source: Tables AE6 and AE7		

Table 17a. Number of Patients (>5% of Patients) Reporting Adverse Events by COSTART Term in Part 2

Body System/COSTART Term	Number of Patients Reporting Event (%)	
	Reboxetine	Placebo
Body		
Abdominal pain	2 (8.3%)	2 (9.1%)
Back pain	0	2 (9.1%)
Fatigue	2 (8.3%)	<5%
Fever	2 (8.3%)	0
Flu Syndrome	<5%	2 (9.1%)
Headache	5 (20.8%)	4 (18.2%)
Localized pain	2 (8.3%)	4 (18.2%)
Upper respiratory infection	2 (8.3%)	3 (13.6%)
Cardiovascular		
Hypertension	2 (8.3%)	0
Musculo-Skeletal		
myalgia	0	3 (13.6%)
Nervous		
Dizziness	0	4 (18.2%)
Insomnia	0	2 (9.1%)
Nervousness	2 (8.3%)	0
Paresthesia	4 (16.7%)	0
Respiratory		
Pharyngitis	<5%	2 (9.1%)
Sinusitis	0	2 (9.1%)
Special Senses		
Blurred vision	2 (8.3%)	0
Tinnitus	2 (8.3%)	0

Source: Table AE16
Information on drug-related adverse events for placebo and reboxetine treatments in Part 2 are presented in appendix Table AE16a.

10.4.2. Deaths, Serious Adverse Events, and Other Significant Adverse Events

10.4.2.1. Deaths

There were no deaths in this study.

10.4.2.2. Serious Adverse Events

Serious adverse events were reported for five patients in this study. Three reports occurred in Part 1 and two (one in the reboxetine group and one in the placebo group) in Part 2. The reports are summarized in Table 18. With the exception of the suicide attempt in patient 211147, the opinion of the investigator was that the event was not related to study drug. All of the patients recovered with the exception of patient 191014 whose tumor became chronic/stable.

Table 18. Summary of Serious Medical Events

Patient Number	Study Part	Treatment	Event Verbatim	Related to Study Medication
81052	1	Reboxetine	Alcohol relapse	No
201092	1	Reboxetine	Suicidal depression	No
211147	1	Reboxetine	Suicide attempt	Yes
151038	2	Placebo	Cancer (bladder)	No
191014	2	Reboxetine	Brain tumor	No
Source: Table AE17				

The narratives for these five patients follow.

Part 1 – Open-Label Reboxetine

Patient Number 81052 (Investigator – Helfing)

Events: Alcohol relapse

This 39 year old female patient with a history of major depression was entered into the study on September 17, 1999. Open label reboxetine (8 mg/day) treatment was initiated. An improvement in her symptoms of depression were noted one week later (September 23). Over the next two days, she reported being overcome by emotional stressors (child custody battle and financial problems) and resumed drinking alcohol. Her depression worsened and she was admitted to inpatient psychiatry on September 26. During the hospitalization, reboxetine was discontinued and she was started on valproate (250 mg twice daily), lithium (no dose provided) and trazadone (100 mg nightly). She was discharged from the hospital on October 4, 1999. She was not restarted on reboxetine and was discontinued from the protocol. These events were not considered related to reboxetine.

Patient Number: 201092 (Investigator – Zajecka)

Events: Suicidal depression

This 41 year old female patient with a history of major depression was entered into the study and therapy with open label reboxetine (8 mg/day) begun on February 22, 2000. On March 22, the woman was hospitalized with suicidal depression, plan and intent. The reboxetine was discontinued. These events were not considered related to reboxetine.

Patient Number: 211147 (Investigator – Dunner)

Events: Suicide attempt

This 37 year old female patient with a history of major depression was entered into the study on February 22, 2000. Open-label reboxetine (8 mg/day) was begun on February 22. On March 1, the patient attempted suicide by carbon monoxide poisoning. She was hospitalized in stable condition; reboxetine was permanently withdrawn. The patient was started on

Effexor on March 3 and discharged from the hospital on March 7. The patient was seen on March 14 and was feeling better with improvement in suicidal thinking and with no suicidal plans. The investigator thought there were three possibilities with regard to the event being related to reboxetine:

The first possibility was that fluoxetine, which the patient was taking just prior to study entry, was partially effective and its discontinuation lead to worsening depressive symptoms leading to the suicide attempt.

The second was that reboxetine, which the patient had taken for about a week, had not yet had a chance to work.

Lastly, reboxetine may have caused an increase in suicidal ideation.

The investigator felt that the first two alternatives were likely and that the third was not likely, but could not be ruled out. The sponsor's clinical team reviewed the event and deemed it related to reboxetine.

Part 2 – Double Blind; Reboxetine Group

Patient Number: 191014 (Investigator – Trivedi)

Events: Brain tumor

This 47 year old male patient with a history of major depression was entered into the study and open-label reboxetine treatment initiated (8 mg/day) on October 28, 1999. Occasional headaches were noted in the medical history. The patient completed Part 1 of the study and was subsequently randomized to blinded-reboxetine in Part 2 of the study. On February 3, 2000, the patient's wife noted changes in the patient's speech and enunciation. Study medication was discontinued on that day. On February 7, a MRI revealed a brain tumor. The patient denied headaches, nausea and vomiting and felt well. He experienced poor sleep and increased anxiety with no changes in energy or motivation. He was not suicidal. He reported problems with balance. He was subsequently diagnosed with glioblastoma. The patient would not approve further follow-up with the treating neurologist. These events were not considered related to reboxetine.

Patient Number: 151038 (Investigator – Rapaport)

Events: Cancer (bladder)

This 52 year old male patient with a history of major depression completed 8 weeks of open-label reboxetine and was entered into Part 2 of the study on December 13, 1999. He was randomized to placebo. The patient had previously had surgery to remove bladder cancer in August 1999. On February 1, 2000, the patient was again diagnosed with bladder cancer. The tumor was removed on February 16. Study drug was continued unchanged. These events were not considered related to study drug.

10.4.2.3. Discontinuations Due to Adverse Events

Part 1 – Twenty-one patients discontinued from Part 1 because of adverse events. Events leading to discontinuation in >1% of patients are listed in Table 19. With the exception of one symptom (insomnia), no other symptoms lead to the discontinuation of more than four subjects. The symptom cluster that led to the discontinuation of each subject is listed in Table AE10.

Table 19. Adverse Events Leading to Discontinuation in >1% of Patients in Part 1

Preferred COSTART Term	Number of Patients	% Patients
Total patients discontinuing because of adverse events*	21	16.4
Abdominal cramp	2	1.6
Chills	2	1.6
Vasodilation	2	1.6
Constipation	4	3.1
Nausea	2	1.6
Anxiety	2	1.6
Dizziness	2	1.6
Insomnia	8	6.3
Manic symptoms	2	1.6
Diaphoresis	2	1.6
Abnormal ejaculation	3	2.3
Impaired urination	2	1.6
* Some patients had more than 1 symptom reported at the time of discontinuation. *Source: Tables AE8 and AE10*		

Part 2 – The only patient who discontinued because of adverse events in Part 2 is a male in the reboxetine group who was diagnosed with a brain tumor (see case number 191014 previously reported in Section 10.4.2.2).

10.4.3. Clinical Laboratory Evaluation

Serum chemistries, hematological evaluations and urinalyses were performed at screen and at weeks 4, 8 and 32. In addition, a urine drug screen was performed at baseline, at week 8 and the final evaluation. Samples were centrally analyzed by SmithKline Beecham Clinical Laboratories. The results are reported in Tables LAB1 through LAB17.

Results from the urine drug screen are documented in Tables LAB12 (Part1) and LAB13 (Part2). Tests in Part 1 are almost uniformly negative. Marijuana metabolites were detected in 1 patient at baseline and at Week 8. Opiates were detected in 4 patients at baseline and 2 at Week 8. In addition, cocaine metabolites were detected in 1 patient at Week 8. Tests in Part 2 were all negative. Table LAB17 lists all positive tests.

The results from hematology assays are listed in Tables LAB1, LAB2 and LAB3 (Part1) and LAB4 (Part 2). Patients with abnormal hematology values are listed in Table LAB14. In Part 1, there were several clinically insignificant but statistically significant changes in laboratory assays (LAB2). These included hematocrit (p=0.018; week 4 only), RBC count(p=0.025; week 4 only), WBC count (p=0.025; week 4 only), total neutrophils (p=0.002; Week 4 only), monocytes % (p<0.001; week 4 only), eosinophils % (p<0.001; week 4 and p=0.021; week 8) and platelet count (p=0.026; week 8). The number of patients whose tests shifted from normal to either a low or high range was quite small (LAB3). In many cases additional follow-up testing again provided results within the normal range. Lastly, there were no apparent differences between the reboxetine and placebo groups in Part 2 (Table LAB4).

Tables LAB5 through LAB8 and LAB15 provide the results from the clinical chemistry assays in this study. There were only three small statistically significant changes among these variables (LAB5). These were: uric acid (p=0.020; week 8 only), reticulocyte count (p=0.006; week 8 only) and CO2 (p=0.004; week 4 only). The number of patients whose tests shifted from normal to either a low or high range was quite small (LAB7). In many cases additional follow-up testing again provided results within the normal range. Lastly, there were no apparent differences between the reboxetine and placebo groups in Part 2 (Table LAB8).

Results from the urinalysis assays are reported in Tables LAB9, LAB10, LAB11 and LAB16. Statistical tests were not conducted on these variables. However, there were no apparent consistent clinically significant changes in Part 1 (Table LAB9 and LAB10) or differences between the treatment groups in Part 2 (Table LAB11). Individual patient data are listed in Table LAB16.

10.4.4. Vital Signs

Vital signs (weight, systolic and diastolic blood pressure, sitting pulse, temperature and respiration rate) were recorded at each visit during the study.

Part 1 - Tables VS1 through VS9 document the results of the vital signs that were recorded during Part 1. With the exception of the pulse rate there were no clinically meaningful changes in any vital sign (Tables VS1 and VS2). While there were a few statistically significant changes in weight, systolic blood pressure and temperature, these were quite small and random in their temporal pattern (see Table 19). However, the sitting pulse increased by approximately 7 beats per minute by the end of the first week of treatment (p<0.001) then plateaued (9 to 11 bpm increase) and remained elevated for all 8 weeks (p<0.001 at each week). Clinically significant increases in pulse rate were recorded in four individual patients (Table VS9). Again, these were random in time and decreased despite continued treatment.

Table 19. Significant Changes in Vital Signs in Part 1

Vital Sign	Study Period	Number of Patients	Mean Change	p-Value
Weight (pounds)	Week 2	114	-0.6	0.049
Systolic blood pressure (mm Hg)	Week 2	116	-2.1	0.041
	Week 3	108	-2.4	0.031
Temperature (°F)	Week 3	104	-0.2	0.016
	Week 7	84	-0.3	0.004
Sitting pulse (bpm)	Week 1	123	7.4	<0.001
	Week 2	116	8.5	<0.001
	Week 3	108	8.5	<0.001
	Week 4	106	11.3	<0.001
	Week 5	100	9.6	<0.001
	Week 6	96	11.6	<0.001
	Week 7	87	11.0	<0.001
	Week 8	79	11.0	<0.001
Source: Table VS2				

Part 2 – Tables VS3 through VS8 record the vital sign data for weeks 8 through 32. There is an apparent decrease in the mean pulse rate in the placebo group.. No other notable changes occurred.

10.4.5. Electrocardiograms

Twelve lead electrocardiograms (ECGs) were performed at screening, week 4, week 8 and week 32. Analysis included assessment of abnormal ECG patterns and measurement of appropriate intervals. All ECGs were submitted to a central facility (Premier Research Worldwide) for evaluation. Tables ECG1 through ECG8 report the results of the ECGs recorded during the study.

Tables ECG1 and ECG2 document the results of the intervals during Part 1 of the study. Small but statistically significant decreases in the PR, RR QT and QTc (Bazett correction) intervals occurred at both weeks 4 and 8 (Table ECG2). These were accompanied by a significant increase in heart rate at both time periods. Statistically significant increases in sitting pulse (mean 11.0 beats per minute) and ECG heart rate (mean of 15.9 beats per minute) were observed by Week 8. There were no other clinically meaningful changes in laboratory parameters or vital signs. Only one patient whose ECG pattern was normal at screen exhibited an abnormal pattern at the week 8 follow-up (Table ECG3).

The results of recordings made in Part 2 are summarized in Tables ECG4 through ECG6. Patients in the placebo group exhibited a significant increase in the RR and QT intervals as well as a decrease in heart rate (Table ECG5). There were no changes with regard to normal/abnormal patterns (Table ECG6).

Tables ECG7 and ECG8 provide a listing of abnormal ECGs recorded in this study.

10.4.6. Safety Conclusions

The switch from fluoxetine to reboxetine was safe and without significant clinical sequelae. The frequency of occurrence of adverse events as well as their qualitative nature appeared to be similar in this study as compared to previous clinical experience with reboxetine.

Adverse events were reported in almost all (97.7%) of the patients in the open label portion of this study. Many of the events reported (eg, fatigue, , insomnia, etc) are also common symptoms of Major Depression and thus may be related to the disease itself. Serious events were reported by five patients in the study, including three in Part 1 and two (reboxetine = 1; placebo = 1) in Part 2. Only one of these was thought to be potentially related to reboxetine treatment.

The most common adverse events occurring in Part 1 were: headache, insomnia, constipation, dry mouth and diaphoresis. These events were most commonly reported as mild or moderate in intensity. Twenty one patients discontinued from Part 1 of the protocol because of adverse events. The most common event leading to dropout was insomnia (8 patients). The occurrence of adverse events in Part 2 was only somewhat higher in the reboxetine group (79.2%) as compared to the placebo group (68.2%). There were no specific symptoms that seemed to occur more frequently in the reboxetine group.

There were no changes in clinical laboratory measures that appeared to occur more often in the reboxetine group. Statistically significant changes were small, occurred randomly in time and usually reversed even with continued treatment. Similarly, most of the vital signs recorded during the study exhibited no consistent drug-induced changes. However, pulse rate increased upon initiation of reboxetine treatment and remained elevated throughout the treatment period. Further, the rate appeared to decrease in those patients after being randomized to placebo in Part 2.

The vital sign data were confirmed by the ECGs recorded during the study. Statistically significant increases in sitting pulse (mean 11.0 beats per minute) and ECG heart rate (mean of 15.9 beats per minute) were observed by Week 8. There were no other clinically meaningful changes in laboratory parameters or vital signs. The increases in sitting pulse and ECG heart rate observed in this study are consistent with those observed in Phase II/III clinical trials with reboxetine. Increases in sitting pulse rate (mean of 6.4 beats per minute) and ECG heart rate (mean of 6-12 beats per minute) have been observed in the general adult population and, as such, caution is indicated with administering reboxetine to patients with compromised cardiovascular conditions.

11. DISCUSSION AND OVERALL CONCLUSIONS

The results from Part 1 of the study clearly demonstrated that reboxetine was effective in treating patients who are partial responders to fluoxetine treatment. Approximately half of the patients enrolled in this study experienced at least a 50% decrease in their 25-Item Hamilton Depression Rating Scale score at the end of eight weeks of treatment with reboxetine on an open-label basis. These results were mirrored by those of the Montgomery

Asberg Depression Rating Scale as well as the clinician's and patient's global evaluations. In addition, virtually all of the individual Hamilton Depression Scale items showed significant improvement by the end of the eight week period.

The safety evaluations from both parts of this study demonstrated that it is safe to immediately switch from fluoxetine to reboxetine. The occurrence of adverse events were qualitatively and quantitatively similar to those reported in previous reboxetine studies. Adverse events occurred most often during the first four weeks of treatment and then sharply decreased. Only increased pulse occurred consistently during reboxetine treatment. Statistically significant increases in sitting pulse (mean 11.0 beats per minute) and ECG heart rate (mean of 15.9 beats per minute) were observed by Week 8. There were no other clinically meaningful changes in laboratory parameters or vital signs. The increases in sitting pulse and ECG heart rate observed in this study are consistent with those observed in Phase II/III clinical trials with reboxetine. Increases in sitting pulse rate (mean of 6.4 beats per minute) and ECG heart rate (mean of 6-12 beats per minute) have been observed in the general adult population. Caution is indicated with administering reboxetine to patients with compromised cardiovascular conditions. The results from Part 1 show that it is clear that patients taking fluoxetine may safely transfer to reboxetine treatment as desired.

Part 2 of the study failed to show statistically significant superiority of reboxetine over placebo in terms of the time to relapse during double blind treatment. These results are in contrast to a previous study [14] which clearly showed that reboxetine is significantly more effective than placebo in preventing relapse from MDD. The reason(s) for the difference in results cannot be completely explained at this time.

12. ACKNOWLEDGMENTS

The interim analyses were carried out by Kerry Barker who was not involved in the final analyses of the results. The final analyses of the Quality of Life variables (SF36 and SASS) were done by Clayton Roland.

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PRODUCT: Reboxetine (PNU-155950E)

PROTOCOL No: M-2020-0034

STATUS: Final DATE: 12 March 1999

PROTOCOL TITLE: Reboxetine (PNU-155950E) vs placebo in the treatment of Major Depressive Disorder Resistant to Fluoxetine

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Table of Contents

1. PROTOCOL SUMMARY

Protocol Number:	M-2020-0034
Protocol Title:	Reboxetine (PNU-155950E) vs placebo double-blind treatment of Major Depressive Disorder Resistant to Fluoxetine
Study Objective:	To assess the safety and efficacy of reboxetine vs placebo in the treatment of patients with Major Depressive Disorder resistant to fluoxetine and responding to reboxetine
Study Design:	Randomized discontinuation study of reboxetine vs placebo in fluoxetine failures responding to reboxetine
Study Medication and Dosage Form:	1) Reboxetine scored 4 mg tablets 2) Placebo tablets, matching 1) above
Route of Administration:	Oral
Dose Regimen:	**Part 1**. Weeks 1-4: - Reboxetine 4 mg capsule twice daily (morning and evening) Weeks 5-8: - optional dosage increase to reboxetine 10 mg/day total dose by addition of 1/2 tablet (2 mg) in the evening to above regimen **Part 2**. Week 9-32: Responders will be randomized to continue the Day 57 reboxetine dose or begin placebo, continuing on a twice daily schedule
Duration of Treatment:	8 weeks open label reboxetine follow by randomization to double-blind treatment until relapse or study completion at week 32
Duration of Subject Participation in Study:	8-1/2 month maximum
Duration of Study:	30 months
Number of Subjects Required to Meet Protocol Objectives:	100
Anticipated Maximum Number of Subjects:	200
Number of Investigators:	Approximately 20

2. ABBREVIATIONS AND DEFINITIONS OF TERMS

RBX = reboxetine (the compound is further described in the Investigator's Brochure)
PLC = placebo
FLX = fluoxetine (sold by Eli Lilly as Prozac)
SSRI = selective serotonin reuptake inhibitor
NRI = noradrenaline reuptake inhibitor
DSM-IV = Diagnostic and Statistical Manual for Mental Disorder, 4th Edition
MDD = major depressive disorder
CRF = case report form(s)
HAMD = Hamilton Rating Scale for Depression
CGI = Clinical Global Impression
PGI = Patient Global Impression
KSQ = Kellner Symptom Questionnaire
SCID = Structured Clinical Interview for DSM-IV Axis I Disorders
____ = Mass. General Hospital Scale

Note: Definition of these and many other abbreviations are included in the text of the protocol

3.0 BACKGROUND INFORMATION

Reboxetine

Reboxetine (RBX) is a specific noradrenaline reuptake inhibitor (NRI), highly potent in rodent models predictive of antidepressant activity in humans (e.g. reserpine antagonism, clonidine effects prevention, REM sleep latency increase). RBX has no relevant affinity for the serotonin and dopamine uptake sites or for muscarinic cholinergic or adrenergic receptors. On the basis of RBX effects in the models predictive of antidepressant activity and of the relative absence of pharmacological properties reportedly responsible for the side effects of classical antidepressant agents, the compound was evaluated for the treatment of depressive disorders [1].

RBX has undergone extensive preclinical and clinical evaluation, primarily in Europe and Latin America, as a potential treatment for Major Depressive Disorder (MDD) [1-11]. The program included four placebo (PLC) controlled short term (4 to 8 week) studies and three uncontrolled short term studies in the adult population. Comparator antidepressants were included in three of the placebo controlled studies. Elderly patients were studied in two uncontrolled, one placebo controlled and one imipramine controlled short term studies. Additionally, long term studies (up to one year) were conducted in both adults and elderly patients. A total of 2,613 patients have been treated; 1,503 with RBX, 399 with placebo (PLC), and 711 with comparator antidepressant drugs (desipramine {DMI}, imipramine {IMI} and fluoxetine {FLX}). The typical RBX doses ranged from 8 to 10 mg/day in the adult population.

The results of these studies support the following conclusions:

- Three of the PLC-controlled studies (study 091 [13], study 008 [11], study 014 [9]) demonstrated the efficacy of RBX on the study endpoint (ie mean reduction of the Hamilton Rating Scale for Depression {HAMD} total score or response rate is ≥50% decrease in HAMD total score), according to the hypothesis stated in the study protocols. The fourth PLC-controlled study (study 015 [10]) showed greater efficacy for RBX and for IMI than for PLC, but the differences between the active treatments and PLC on the study endpoint did not reach statistical significance. However, subpopulation analysis, particularly of the severely ill patients but also of the melancholic patients, showed the efficacy of RBX and IMI on the study endpoint.
- Selection of the RBX dose regimens was accomplished in an early phase II, non randomized, dose-finding study (study 004 [8]), which was adequate to identify the daily dose associated with intolerance in a proportion of patients (12 mg/day) and the daily doses associated with minimal side-effect and maximal response rates (8 and 10 mg/day), although, in view of the non-randomized conditions, no conclusions about dose-response could be drawn. However, further support of the appropriateness of the selected dose regimens is derived from the results of the phase III studies, which show that a dose of 8 mg/day is suboptimal in a proportion of patients in whom increasing the

dose to 10 mg/day resulted in clinical response. Daily doses lower than 8 mg are unlikely to be maximally effective.

- While the frequency of response was greater for RBX (60%) than for DMI (44%) in the DMI- and PLC-controlled study [11] (between-treatment difference, 16%; 95% CI, 9%-31%), no major differences were apparent in the cumulated analysis of the IMI-controlled and FLX-controlled studies in the adult patients in either the frequency or extent of clinical improvement. The same analysis on the subset of severely ill patients indicated no major differences between RBX and IMI and, primarily due to the results of the non-PLC-controlled study, some advantage for RBX over FLX in terms of extent of clinical improvement.

Eleven serious adverse events were reported for 11 (0.9%) RBX-treated patients; 6 serious adverse events were reported for 6 (2.5%) of the IMI-treated patients; 2 serious adverse events were reported for 2 (0.9%) of the FLX-treated patients; and 4 serious adverse events were reported for 4 (0.8%) of the PLC-treated. The most frequent serious adverse events were related to psychiatric disorders, CNS disorders, cardiovascular system disorders, and other body systems disorders. Death occurred only as a result of suicide. There were 2 suicides in 1247 RBX-treated patients (0.2%), and 1 suicide in 513 placebo-treated patients (0.2%). There was therefore no difference in suicide rate between these two groups. There were 2 suicide attempts in 1247 RBX treated patients (0.2%) and 2 suicide attempts in 513 placebo treated patients (0.4%). There was one case of parasuicide by overdose of RBX. There was one case of accidental overdose of chloral hydrate with complete recovery in a RBX-treated patient. The other serious adverse events of RBX-treated patients are as follows. Two patients in the RBX group suffered from convulsions that in each case could have been promoted by a pharmacodynamic interaction between the antidepressant and a concomitantly administered neuroleptic. One (0.1%) patient in the RBX group, who had no history of cardiovascular disorders, suffered from myocardial ischemia after 42 days of treatment with RBX. At the time of the event, the patient had temporarily discontinued the RBX therapy. One patient developed jaundice after 21 days of treatment with a daily dose of 8 mg of RBX. At entry to the study, he was reported to have gallstones, hyperlipidemia, and hypertension and to abuse alcohol. One patient was found to have a left ovarian cyst after 22 days of treatment with a daily dose of 8 mg of RBX.

Among the most frequently reported adverse events (ie, events reported by ≥2% of the patients who were treated with RBX), the following were reported more frequently by the RBX-treated patients than by the PLC-treated patients: dry mouth (27% versus 16%), constipation (17% versus 10%), increased sweating (14% versus 7%), insomnia (14% versus 5%), hypotension and related symptoms (11% versus 8%), urinary hesitancy/retention (5% versus 2% of which retention constituted 2% and 1%, respectively), blurred vision (5% versus 3%), tachycardia (5% versus 2%), tremor and anorexia (4% versus 3% for each event), paraesthesia (4% versus 2%), vertigo (2% versus 0%), decreased libido and flushing/hot flushes (2% versus 1% for each event), and impotence (5% of the male RBX-treated patients versus 0% of male PLC-treated patients).

The majority of patients with adverse events in the PLC group reported events that were mild in severity (45% of the patients reported events of mild severity, 38% reported events of moderate severity, and 16% reported events of severe severity), whereas the majority of patients with adverse events in the RBX group reported events that were moderate in severity (44% of the patients reported events of moderate intensity, 32% reported events of mild severity, and 23% reported events of severe severity). No relevant gender- or age-related differences were apparent.

Since this trial will focus on reboxetine treatment of patients with depression who have been previously treated with fluoxetine, a discussion of adverse events in the two previous FLX-controlled studies is warranted. Two hundred five patients (142 females and 63 males) received RBX and 216 patients (147 females and 69 males) received FLX in the two FLX-controlled studies (study 014 [9], study 016 [16]). Among those patients who reported adverse events, the mean number of events was 3.5 for patients in the RBX group and 2.9 for patients in the FLX group.

Among the most frequently reported events (reported by ≥5% of exposed patients in at least one treatment group), the events that were more frequently reported by RBX-treated patients than by FLX-treated patients were as follows: dry mouth (27% versus 7%), constipation (17% versus 5%), insomnia (16% versus 11%), hypotension and related symptoms (13% versus 6%), increased sweating (12% versus 7%), impotence (10% versus 4% of the male patients), paraesthesia (6% versus 1%), and urinary hesitancy/retention (6% versus 1% of which retention constituted 1.5% and 0%, respectively). Adverse events that were more frequently reported by the FLX-treated patients than by the RBX-treated patients were nausea and related symptoms (26% versus 15%), headache/migraine (20% versus 14%), tremor (7% versus 4%), diarrhea (7% versus 2%), and somnolence (5% versus 1%).

The majority of patients with adverse events reported events of moderate severity in both the RBX (43% of the patients with adverse events) and FLX (54% of the patients with adverse events) groups; however, at least one severe event was reported by 25% of the patients with adverse events in the RBX group (17% of the exposed) and by 17% of the patients with adverse events in the FLX group (11% of the exposed). No relevant gender- or age-or diagnosis-related differences were apparent.

<u>Summary of Long-term study of particular importance to the current study</u>

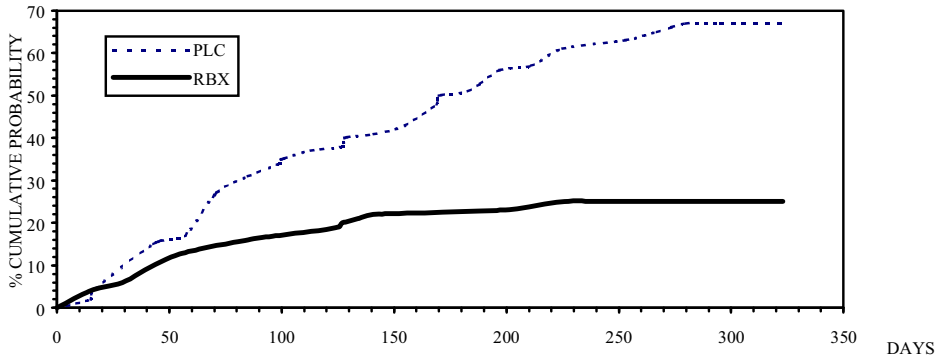
A previous trial with reboxetine (ADE 013) [17] has been conducted with a double-blind discontinuation comparison of reboxetine and placebo in MDD responders to reboxetine. This phase III, PLC-controlled study was conducted to evaluate the long-term maintenance of the response that was obtained during short-term RBX treatment. Acutely ill patients with a recurrence of MDD and a total 21-item HAMD score of 18 or greater received treatment with RBX 4 mg BID for 6 weeks; at the end of this 6 week period, patients who responded to treatment (≥50% decrease of HAMD total score versus baseline) were randomized to treatment with RBX or PLC until relapse (defined as ≥ 50% increase of HAMD total score

versus week 6 associated with a total score of at least 18) occurred or for a maximum treatment period of 1 year.

Three hundred fifty-eight patients were admitted to the study and treated with RBX for 6 weeks; 286 patients (80%) were then randomized to double-blind treatment with RBX (n=145, of which 143 received treatment) or PLC (n=141, of which 140 received treatment). The two groups were similar to the population that was admitted into the study and were well balanced for demographic and anamnestic features: Females were more common than males in both groups (79% of the patients in the RBX group and 67% of the patients in the PLC group); the average age at admission was 43 years in the RBX group and 42 years in the PLC group. According to protocol provisions, all but one patient was suffering from a recurrence of MDD, with an average number of previous episodes of 3.4 in the RBX group and 3.0 in the PLC group. At admission, the mean duration of the index episode was 13.9 weeks in the RBX group and 15 weeks in the PLC group.

Among the 133 responder patients who were randomized to RBX, 22% relapsed (at least once) during long-term treatment, whereas, among the 132 responder patients who were randomized to PLC, 56% relapsed; the difference between treatments in relapse rate was highly significant ($p<0.01$). The cumulative risk of relapse (Kaplan-Meier analysis) in the 133 and 132 patients who were randomized to RBX and PLC, respectively, and who complied with the protocol response criterion is summarized in Figure 1. Again, the between-treatment difference (log-rank test) was highly significant ($p<0.0001$).

Figure 1. Cumulative Risk of Relapse*



***** Based on Kaplan-Meier methods; N = 132 for PLC and 133 for RBX

Abbreviations: PLC = placebo, RBX = reboxetine

An additional analysis was performed to evaluate the proportion of relapse-free patients during the first and the last 6 months of treatment. The purpose of this analysis was to investigate the rate of relapse of the index episode and the rate of recurrence of a new episode in the two treatment groups. The results of this analysis are summarized in Table 1.

Table 1. Proportion of Relapse-Free Patients After 6 and 12 Months of Treatment

	RBX			PLC			
		Relapse-Free			Relapse-Free		
Months	**n**	**n***	**%**	**n**	**n***	**%**	**χ^2 test**
1-6	133	81	60.9	132	53	40.2	11.4
7-12	75	66	88.0	49	29	59.2	13.7

* Patients who did not relapse at least once during the indicated period and who did not withdraw because of improvement are included.

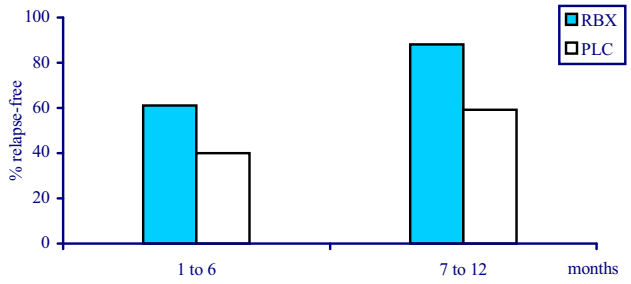
Abbreviations: PLC = placebo, RBX = reboxetine

Among the 133 who were randomized to RBX and the 132 patients who were randomized to PLC and who complied with the protocol response criterion, 61% and 40%, respectively, remained relapse-free in the initial 6 months of treatment following randomization (p=0.001), thus proving the efficacy of RBX in the prevention of relapse of the index episode. Among the 75 and 49 patients in the RBX and PLC groups, respectively, who entered into the last 6 months of treatment, 88% and 59%, respectively, remained relapse-free up to the end of

treatment ($p<0.001$), thus suggesting the efficacy of RBX in the prevention of recurrences of new episodes. These data are summarized in Figure 2.

Figure 2. Proportion of Relapse-Free Patients

After 6 and 12 Months of Treatment



Abbreviations: PLC = placebo, RBX = reboxetine

In conclusion, the results of this PLC-controlled study proved the efficacy of RBX in the maintenance therapy of MDD. As measured by the HAMD, MADRS, and CGI scales, RBX was markedly superior to PLC for the maintenance therapy of patients with MDD when administered for up to 1 year. The tolerability of long-term administration of RBX was highly acceptable, as shown by the safety profile.

Full details of these previous studies are summarized in the current Investigator Brochure.

<u>New data relative to combined reboxetine/fluoxetine therapy</u>

In this protocol, patients who have not responded to fluoxetine will be switched to open-label treatment with reboxetine. Because fluoxetine has a prolonged elimination half life, during the first several weeks of reboxetine treatment, the patient will effectively be exposed to both fluoxetine and reboxetine. Study 053 has examined the safety of combined administration of reboxetine and fluoxetine in healthy volunteers. In this study 30 healthy volunteers were randomized into one of three treatment groups. Three separate treatments were administered to the three groups of 10-11 subjects: reboxetine 8 mg/day & placebo (n=11), placebo & fluoxetine 20 mg/day (n=10), and reboxetine 8 mg/day & fluoxetine 20 mg/day (n=10) for 8 days. Patients were evaluated daily for possible adverse events. Vital signs were monitored on Day 1 and on Day 8 both prior to and following drug administration. Blood and urine samples were collected for safety laboratory evaluations at screen, pre-dose on Day 1 and again pre-dose on Day 8. Pharmacodynamic parameters were assessed on Day 1 and Day 8. Pharmacokinetics were performed on Day 8. Performance testing with the Digit Symbol Substitution Test (DSST), a neuropsychological measure used for screening neurocognitive dysfunction, was

administered on Day 1 (pre-dose), Day 7 and Day 8 (pre-dose). Preliminary data analysis of this trial reveals that there was no evidence for any interaction between reboxetine and fluoxetine on any clinical measure including adverse events. None of the treatments had significant effects on the laboratory results or body temperature. In all treatments, performance on the DSST improved over time. There were no significant differences among treatments. Reboxetine had the expected effects on blood pressure and pulse, but fluoxetine did not appear to potentiate these effects. No statistically significant pharmacokinetic or pharmacodynamic interaction was observed [48].

Patients failing to respond to fluoxetine therapy

There is clearly a subset of patients with MDD that does not respond to treatment with selective serotonin reuptake inhibitors (SSRI). This statement is based upon our experience above and documented in the psychiatric literature. Estimates in the literature state that roughly 20-30% of patients with depression will fail to respond to a trial of antidepressants [25]. Typically 33% to 50% of patients who begin a trial of an SSRI will be unable to tolerate therapeutic doses or are unresponsive to an adequate trial [26, 27, 28]. Some patients initially unresponsive to standard doses of an SSRI may respond when the dose is escalated [29]. Treatment options for patients who fail an SSRI generally consists of augmentation therapy, changing to another antidepressant within the same class, or changing to a different class of antidepressant [26].

Few reports have examined patient response to a second SSRI following poor response to an initial SSRI. A detailed definition of what constitutes SSRI nonresponse (e.g. SSRI intolerance vs lack of SSRI efficacy) is often missing. The reports are a combination of retrospective analyses or uncontrolled clinical trials. Brown and Harrison [31] enrolled 113 major depression patients who had discontinued FLX because of side effects into an open label 8 week study of sertraline's tolerability and efficacy. Patients who discontinued FLX due to lack of efficacy were not evaluated in this study. They found that 79 (71.8%) of 110 patients evaluated for efficacy were "much" or "very much" improved on the Clinical Global Impressions (CGI) Scale relative to baseline. Only 11 (9.8%) of 112 patients discontinued sertraline because of adverse reactions. The authors concluded that patients who discontinue one SSRI because of side effects can be successfully treated with another. Zarate [30] retrospectively identified 42 inpatients with MDD, bipolar depression, schizoaffective disorder and obsessive compulsive disorder who were treated with sertraline after previously failing FLX treatment. The definition of FLX failure were not described in detail, though 21/39 (54%) discontinued FLX due to adverse effects. In those patients with major depression (N=25) and bipolar depression (N=6), only 13 (42%) were considered responders to sertraline therapy, and at mean 7 month follow-up only 8 (26%) were considered responders. The authors concluded that sertraline was modestly efficacious and associated with numerous side effects and high discontinuation rates in patients who had discontinued fluoxetine. Thase [26] performed a prospective clinical trial of the converse treatment paradigm, treating patients who had not responded to sertraline with FLX. In this study, adult outpatients (N=106) with major depressive disorder and a history of either intolerance (N=34) or nonresponse (N=72) to treatment with sertraline were treated with open label FLX (mean dose=37.2 mg/day) in a standardized 6 week clinical trial. Sixty seven patients (63%) responded to FLX. FLX was generally well

tolerated and there were only slight differences in adverse events reported by patients who had been intolerant to sertraline versus those who were nonresponders. Thase postulated that the more positive results of his study compared to Zarate's study [30] may have been due to Zarate's inpatient population which was probably more severely depressed, treatment resistant and markedly comorbid. Joffee [32] retrospectively reviewed a database for a mood disorders program within a university hospital and identified 55 patients with major depression who had failed to respond to the first SSRI used, based on the CGI Improvement scale. Minimum doses of antidepressant used was 20 mg/day for FLX, 50 mg/day for sertraline, 100 mg/day for fluvoxamine and 20 mg/day for paroxetine. The minimum duration of the first SSRI trial was 5 weeks and the maximum duration 12 weeks. Following a minimum of 5 weeks on the second SSRI, which was chosen at the discretion treating clinician, 28 of 55 patients (51%) had a marked or complete response, based on CGI Improvement scores. This clinical data was presented as preliminary evidence that patients who fail to respond to one SSRI may respond to a second SSRI.

Although the strategy of switching to another antidepressant within the same class was favored a decade ago when physician choices were primarily limited to tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs), the recent availability of a number of additional classes of antidepressants has lessened the enthusiasm for this strategy [26]. In addition, the results of a recent review suggests that treatment with a second agent within the same class may be less effective than either lithium augmentation or treatment with an alternative class of medication [26,28]. The authors of this review concluded that "Whereas mood disorders have generally been viewed as episodic and of good prognosis, a large subset of this population (45-50%) can be expected to either be intolerant to or fail to respond to an initial medication trial. Evidence to date indicates that a second monotherapy will effectively treat about 40-50% of those who have failed with the initial treatment, especially if the second drug has a pharmacologic profile distinct from the initial medication. The remaining 25% of mood-disordered patients are candidates for one or more augmentation strategies, followed by treatment with an MAOI" [28].

Over a dozen placebo-controlled studies strongly support continuation/maintenance pharmacotherapy of major depression [41,42,43]. More than 50% of patients who discontinue medication treatment during continuation/maintenance will experience a relapse to major depression within six months compared to 20% continued on active medication [38,44,45]. Practice guidelines suggest that continuation/maintenance treatment for four to six months is indicated for patients whose major depression has responded to antidepressant medication [27].

The design of this trial is a double-blind discontinuation trial with survival analysis of reboxetine vs placebo in patients who have failed fluoxetine but responded to open-label reboxetine. This type of trial has been used previously in patients with depressive illness [33]. Advantages include a powerful design which minimizes the number of patients needed for the trial while still utilizing placebo controls, the fact that all patients entering the study are treated with open-label antidepressant medication (ie, no fluoxetine

nonresponders will be initially treated with placebo) and survival analysis with a possible interim analysis which could cause the study to be stopped early.

Centers will enroll patients with a history of failure to respond to fluoxetine in a manner similar to those failing in Fava and McGrath's NIMH study "Prediction of Outcome during Fluoxetine Continuation" [36].

Risks

Patients treated with fluoxetine alone may experience dry mouth, constipation, increased sweating, insomnia, hypotension, impotence, reduced libido, somnolence, nausea, headache and diarrhea. Patients treated with reboxetine alone may experience dry mouth, paresthesia, insomnia, urinary hesitancy/retention, tachycardia, hypotension, impotence, increased sweating, headache, vertigo and constipation. Patients will be switched immediately from fluoxetine (which has a prolonged elimination half life) to reboxetine, so patients will effectively be exposed to both fluoxetine and reboxetine. One study has indicated adverse event profiles were similar between reboxetine alone and reboxetine and fluoxetine treatments [48]. In those patients for whom reboxetine is not effective, there may be risk of worsening of the patient's symptoms of depression. Because reboxetine will be withdrawn from half the reboxetine responders during the randomization period, it is expected some patients will experience a recurrence of symptoms of depression.

Benefits

Patients entering the study will be treated with open-label reboxetine for 8 weeks and may experience improvement in their symptoms of depression. Those continuing reboxetine treatment following randomization may also experience improvement in their symptoms of depression. All study subjects should benefit from pre-treatment physical and laboratory examinations as well as frequent monitoring and evaluation visits.

This product, which was developed in Italy, has been extensively tested throughout the world and approved for marketing in the United Kingdom as Edronax® tablets since April 1997. It has since been approved in ten other European countries and an application to market this drug for depression has been filed with the U.S. Food & Drug Administration. The European approvals have led to some 35,000 prescriptions being filled.

There is a subset of patients with MDD which is resistant to treatment with FLX. There is evidence that reboxetine may have superior efficacy than FLX in severely depressed patients. If reboxetine can be shown to have efficacy and safety in patients with MDD resistant to FLX, this would be an important addition to the available treatment options for this patient population. The objective of the present study is to assess the safety and efficacy of reboxetine vs placebo in the treatment of patients with Major Depressive Disorder resistant to FLX.

Further information is available in the Investigator Brochure [1].

4.0 TRIAL OBJECTIVES

The primary objective is to compare the safety and efficacy of reboxetine vs placebo in the treatment of patients suffering from a Major Depressive Disorder resistant to fluoxetine treatment but responsive to open-label reboxetine. A secondary objective is to assess the safety and determine the response rate of open-label reboxetine treatment in fluoxetine resistant patients with Major Depressive Disorder.

5.0 TRIAL DESIGN

5.1 Primary and Secondary Endpoint

This trial is composed of an initial open-label reboxetine treatment phase (Part 1) and a post-randomization treatment phase only for those patients responding to open-label treatment (Part 2). The primary efficacy measure for each phase is the 25-item Hamilton Depression Rating Scale (25-item HAMD; See Appendix 7) total score. During the open label phase, response will be defined as $\geq$ 50% reduction in total 25-item HAMD score at Day 57 compared to Day 1 and CGI improvement of 1 or 2. HAMD (25-item) total score of < 7 will be considered evidence of remission. Responders who continue in the post-randomization phase will have subsequent 25-item HAMD scores compared to the Day 57 HAMD score. The primary endpoint is the rate of relapse of MDD for patients in the post-randomization phase. Relapse of MDD is defined as $\geq$ 50% increase of 25-item HAMD total score compared to the Day 57 (week 8) HAMD total score, and a minimum HAMD total score of $\geq$ 10 (on the 25-item HAMD). An optional, additional patient visit is allowed within 10 days to re-check the HAMD score once a patient reaches 50%.

A secondary endpoint is time to response/remission in the open-label treatment phase. Secondary efficacy measures are Clinical Global Impression (CGI), Montgomery-Asberg Depression Rating Scale (MADRS) total score, Patient's Global Impression (PGI), and individual items of the HAMD. Additional secondary efficacy measures will include measures of quality of life (QOL) and sexual function. One quality of life scale and one scale exploring social functioning will be used to assess study participants. Respectively, these are the Medical Outcomes Study SF-36 and the Social Adaptation Self-evaluation Scale (SASS). Symptoms will be assessed by using the patient-rated Kelner Symptom Questionnaire (KSQ). A clinical 5-Axis diagnosis will be recorded at the start of the study, and at the end of Parts 1 and 2. Sexual function will be measured using the Rush Sexual Inventory (RSI) Scale.

5.2 Overall Trial Design and Plan

The design of this trial is a double-blind discontinuation trial with survival analysis of reboxetine vs placebo in patients who have failed fluoxetine but responded to open-label

reboxetine. This phase IIIb study will be carried out in approximately 20 centers. Adult patients will be selected from the attending out-patient populations or recruited from the communities. Eligible patients with Major Depressive Disorder (MDD) who have not responded to open-label fluoxetine treatment according to the subject inclusion criteria (see item 6.1) will be treated with open-label reboxetine for eight weeks. Patients who respond to the 8 week open-label reboxetine treatment (Part 1) will be randomized in double-blind fashion to continue the Day 57 dose of reboxetine or to begin placebo treatment (Part 2). Reboxetine non-responders will be withdrawn from the study at or before Day 57. After randomization, treatment will be continued until the patient has evidence of relapse of MDD, completes 6 months of treatment without relapse or withdraws because of adverse events. Efficacy and safety evaluations will be conducted at regular intervals throughout both open-label and post-randomization treatment phases.

5.3 Duration/ Schedule of Events

See flow chart (Appendix 2) for schedule of events.

Patients will be screened for protocol eligibility. Patients eligible to enroll in Part 1 of the protocol will begin open-label reboxetine treatment once consent has been signed and the screening procedures have been verified. Patients eligible for this protocol will have been resistant to at least 6-12 weeks of treatment with fluoxetine (at least 40 mg/day for the last 3 weeks) immediately preceding screening. Upon entry into this study, each patient will be immediately switched to reboxetine without an intervening washout period and will begin treatment with reboxetine 8 mg/day (4 mg BID) on Day 1. Open-label reboxetine treatment will be administered for 8 weeks, with safety and efficacy measures obtained weekly. Beginning with Day 29 of open-label reboxetine treatment, there will be an optional dose increase to reboxetine 10 mg/day (4 mg QAM; 6 mg QPM) for patients, who in the judgment of the investigator have not fully responded to the 8mg/day dose and would tolerate the 10 mg/day dose. On Day 57 (end of 8 week open-label treatment), in addition to ongoing safety monitoring, each patient will be assessed for response to open label reboxetine treatment. Patients who have not responded to open-label reboxetine will discontinue the study. Patients who have responded to open-label reboxetine will be enrolled into Part 2. They will be randomized to continue reboxetine or receive placebo BID in a double-blind fashion. Following randomization all patients will be followed on a weekly basis thereafter for the first 8 weeks (week 9-16), and monthly thereafter until week 32. At visits during the post-randomization phase, safety and efficacy measures will be obtained in the same fashion as during open label treatment. Post-randomization laboratory safety measures will be performed at week 32. Each patient will be maintained on his/her post-randomization treatment until the patient has evidence of relapse of MDD, completes 6 months of treatment without relapse, or withdraws because of adverse events.

6.0 SELECTION AND WITHDRAWAL OF SUBJECTS

Each of the approximately 20 centers will be expected to enroll 10 patients within a period of 12 months, for a total of approximately 200 patients per year overall. We anticipate that

treatment of up to 200 patients may be necessary in the open-label treatment phase to have sufficient patient numbers at the time of randomization to detect significant between-treatment differences.

6.1 Subject Inclusion Criteria

– Patients must be non-responders to open-label fluoxetine under the following conditions:

1. Patients of either sex, of any race, ages 18-65 years
2. Patients must have received open label fluoxetine given daily for at least 6-12 weeks (at least 40 mg/day fluoxetine must have been taken for the last 3 weeks)
3. Non-response to open-label fluoxetine is defined as: a Clinical Global Impression Improvement (CGI-I) score of 3-7 ("minimally improved" to "very much worse") for each of the last two weeks of the fluoxetine treatment while continuing to meet Diagnostic and Statistical Manual-IV (DSM-IV) criteria for Major Depressive Disorder (MDD) without Psychotic Features and a HAMD score of >8 (see Appendix 1).

– At the time of entry into Part 1 patients must:

1. be outpatients with major depressive disorder (MDD) diagnosed with the use of the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID). If the patient had been diagnosed with a complete SCID prior to fluoxetine treatment the Mood Disorders, Mood Episodes, and Psychotic Screen modules will be repeated to confirm the MDD diagnosis (without psychotic features) within 1 week of screening.
2. be evaluated using the 25-item Hamilton Rating Scale for Depression (HAMD) and Addendum at screen and on Day 1 prior to dosing with open-label reboxetine.
3. be receiving fluoxetine
4. provide signed, written informed consent.

6.2 Subject Exclusion Criteria

– DSM-IV diagnosis of Major Depressive Episode with Psychotic Features.
– DSM-IV diagnosis of Cyclothymia Disorder.
– DSM-IV diagnosis of Bipolar I or Bipolar II Disorder
– Meeting criteria for DSM-IV diagnosis of Substance Related Disorders within the past 6 months.
– Meeting criteria for DSM-IV diagnosis of Schizophrenia or Other Psychotic Disorders.
– History of major depressive disorders associated with endocrine disorders: hypo- and hyper-thyroidism tested by TSH and T4; adrenal insufficiency, Cushing's syndrome.
– Positive pregnancy test for women of childbearing potential.
– Females who are breastfeeding

- Refusal by female patients of potential child-bearing age to use effective contraceptives during the study period.
- Participation in any clinical study with an investigational compound in the 4 weeks preceding the study.
- History or presence of gastrointestinal, liver, or kidney disease, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs.
- History of seizures or brain injury; current evidence of clinically important hematopoietic, respiratory or cardiovascular diseases. Current evidence of urinary retention, or glaucoma.
- Any important clinical illness in the 4 weeks preceding the study which might interfere with the conduct of the trial.
- Clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission.
- Electroconvulsive Therapy (ECT) in the previous 6 months.
- High risk of suicide as assessed by Investigator's judgment, score $\geq$ 3 on HAMD suicide item (i.e. suicide ideas, suicide gesture or attempt at suicide), or attempted suicide during the present episode.

6.3 Withdrawal of Subjects

A patient should be withdrawn from the study treatment if, in the opinion of the Investigator, it is medically necessary or if it is the wish of the patient. Termination of test therapy prior to completion of the protocol treatment period may be considered due to adverse events, clinical deterioration or switch to mania, etc.

Patients who fail to respond to the 8 week open-label treatment with reboxetine (Part 1) will be withdrawn from the study. Failure to respond is defined as < 50% reduction in total 25-item HAMD score at Day 57 compared to Day 1. Patients who experience relapse of Major Depressive Disorder during the post-randomization treatment (Part 2) will be withdrawn from the study. Relapse of Major Depressive Disorder is defined as $\geq$ 50% increase of 25-item HAMD total score compared to the Day 57 (week 8) HAMD total score and a minimum HAMD total score of $\geq$ 10 (on the 25-item HAMD). An optional, additional patient visit is allowed within 10 days to re-check the HAMD score once a patient reaches 50%.

In case of treatment discontinuation, the reasons for the withdrawal should be clearly described and the patient should, whenever possible, irrespective of the reason for withdrawal, be examined as soon as possible. Relevant samples (lab tests, ECG and any diagnostic procedure which becomes necessary to define the event leading to withdrawal) should be obtained and all relevant assessments (HAMD, MADRS, CGI, SASS, KSQ, SF36, DSM-IV 5-Axis, "end of treatment" form) should be completed, preferably according to the schedule for final assessment (see Appendix 2: Study Flow Chart). The CRFs should be completed as far as possible and provided to the sponsor.

If a subject does not return for a scheduled visit, every effort should be made to contact the subject. In any circumstance, every effort should be made to document subject outcome, if possible.

7.0 TREATMENT OF SUBJECT

7.1 Trial Medication

Reboxetine tablets will be used for Part 1.
Indistinguishable tablets containing reboxetine or placebo will be used for Part 2.
Placebo will be lactose tablets manufactured by Pharmacia & Upjohn.

The test preparations will consist of:

- Tablets containing 4 mg reboxetine as the free base

- Placebo tablets

Since only patients responding to open-label reboxetine will be continuing on the protocol (i.e. there will be more patients treated on the open-label phase of the protocol), the clinical supplies will be packaged and labeled separately for Part 1 and Part 2 of the study. Treatment for Part 1 will be packaged in bottles and labeled using the open-label patient number. For each patient, 8 bottles labeled with the open-label patient number and the indication “week 1” to “week 8” will be prepared. Each bottle for each week will contain the medication necessary for 1 week plus additional tablets for difficulties in scheduling visits and possible losses (total of 25 tablets), prepared according to the b.i.d. regimen with 1 tablet for the “morning” and 1 tablet for the “evening” dose for weeks 1, 2, 3 and 4 and 1 tablet in the morning and 1 or 1 1/2 tablet in the evening for weeks 5-8. At the time of randomization into Part 2, a second patient number will be assigned for each patient continuing on the study and the post-randomization treatment (reboxetine or placebo) will be labeled using a different color to distinguish Part 2 treatment from Part 1 treatment. The post-randomization treatment will be packaged in bottles and labeled with the post-randomization patient number. For each patient treated post-randomization, 24 bottles labeled with the patient number and the indication “week 9” to “week 32” will be prepared. Each bottle for each week will contain the medication necessary for 1 week plus additional tablets for difficulties in scheduling visits and possible losses (total of 25 tablets), prepared according to the b.i.d. regimen with 1 tablet in the morning and 1 or 1 1/2 tablet in the evening for weeks 9-32 (see Section 7.2 Treatment Schedule).

Drug supplies will be stored at room temperature. All drug supplies will be handled under the direct responsibility of the investigator. The study monitor will check drug storage conditions during site visits.

The investigator will be also responsible for drug accountability and will keep a record of the test compounds received from the sponsor as well as of the dispensed and returned drug. Discrepancies between dispensed and returned study medication should be explained and recorded.

Medication will be dispensed to the patient on the occasion of each visit. On the same occasion, the bottle(s) of the previous supply will be returned by the patient.

All unused medication and empty bottles will be returned to the sponsor at the end of the study.

7.2 Treatment Schedule

Screening
A timeline graph depicting protocol treatment activities is presented in Appendix 4. Patients will be checked for eligibility according to the inclusion/exclusion criteria. Written informed consent will be obtained from each patient. The patients will undergo screening history, physical examination, laboratory and ECG assessments, and specific baseline scales (e.g., HAMD) Information on patients screened for the study and found not to be eligible will be collected in the appropriate screening log.

Part 1 (weeks 1-8)
On Day 1 patients will undergo a baseline assessment of standardized clinical psychopathological evaluations. Patients eligible for the study will begin open-label reboxetine treatment on Day 1 using a reboxetine regimen of 4 mg po BID. During open-label treatment, patients will be assigned patient numbers (to identically match the medication numbers) sequentially as found on the Part I medication boxes (e.g., #1001). Follow-up assessments will be done weekly during the open-label treatment phase.

From Day 1-28 each patient will take one tablet in the AM and one tablet in the PM. Treatment should be administered in the morning and in the evening at an approximately fixed time (e.g., 8 to 9 AM and 5 to 6 PM). From Day 1 to Day 28, patients will receive bottles in which each dose (morning and evening) consists of a tablet containing 4 mg reboxetine as the free base. The dose for these patients will therefore be reboxetine 4 mg po BID.

Patients who are doing well at the 4 week evaluation point will continue the same medication regimen until open-label reboxetine treatment is completed on Day 57. These patients will continue to take their AM and PM doses from bottles in the same way as on Day 1-28.

At the week 4 evaluation, the investigator may increase the patient's daily dose by adding an additional 1/2 tablet (2 mg) each evening to the prior regimen for those patients he believes will benefit in terms of response and will adequately tolerate the increased dose. These patients will generally be those who have had little or no improvement in their

objective measures of depressive symptoms, but no significant difficulty tolerating the starting doses of medication. The dose for these patients from Day 29-57 will therefore be reboxetine 4 mg po QAM and 6 mg po QPM (reboxetine 10 mg/day total). Patients who are dose escalated at Day 28 will continue with the higher dose until completion of treatment on Day 57 unless the patient is unable to tolerate the increased dose, in which case s/he may resume the regimen used in Day 1-28.

On Day 57, each patient will undergo safety and efficacy testing by the investigator. On Day 57, the investigator will determine whether the patient has responded to the open label treatment with reboxetine. **Response is defined as ≥ 50% reduction in total 25-item HAMD score at Day 57 compared to Day 1 and CGI improvement of 1 or 2. Failure to respond is defined as < 50% reduction in total 25-item HAMD score at Day 57 compared to Day 1**. Patients who have not responded to reboxetine will complete end of study forms and discontinue the study on Day 57. Patients who have responded to reboxetine will be eligible to continue into the post-randomization phase of the protocol.

Part 2 (weeks 9-32)
The randomization procedure is described in Section 7.3 below. Investigators will randomize the patient by sequentially assigning the blinded study drug. The number on the Part 2 medication box assigned to the patient will be the post-randomization (Part 2) number for that patient, (e.g., #5001). For all patients who are randomized, both their open-label (Part 1) patient number and their post-randomization (Part 2) number will be collected.

Patients randomized to continue reboxetine will continue taking the same reboxetine dose used on Day 57. From week 9 (Day 57) to week 32, these patients will receive bottles containing reboxetine 4 mg tablets. Patients taking reboxetine 8 mg/day on Day 57, will continue to take 1 tablet po QAM and 1 tablet po QPM (ie 4 mg po BID) from week 9 (Day 57) to week 32. Patients taking reboxetine 10 mg/day on Day 57, will continue to take 1 tablet po QAM and 1 1/2 tablet po QPM (i.e., 4 mg po QAM and 6 mg po QPM) from week 9 (Day 57) to week 32 (Day 225).

From week 9 to week 32, patients randomized to placebo will receive bottles in which each dose (morning and evening) is a placebo capsule. The dose for patients previously taking reboxetine 8 mg/day will therefore be 1 placebo tablet po BID, and the dose for patients previously taking reboxetine 10 mg/day will be 1 placebo tablet QAM and 1 1/2 placebo tablet QPM.

From week 9 (Day 57) to week 32, no dose escalations will be allowed, though an investigator may reduce the dose from 1 tablet QAM and 1 1/2 tablet QPM to 1 tablet po BID in those patients unable to continue tolerating the higher dose.

Following randomization all patients will be followed on a weekly basis thereafter for the first 8 weeks (weeks 9-16), and monthly thereafter (week 18-32) till week 32. At visits during the post-randomization phase, safety and efficacy measures will be obtained in the

same fashion as during open label treatment. Unless a patient withdraws consent, s/he will be maintained on his/her post-randomization treatment until s/he has evidence of relapse of MDD, completes 6 months of treatment without relapse or withdraws because of adverse events.

Relapse of Major Depressive Disorder is defined as ≥ 50% increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10 (on the 25-item HAMD). An optional, additional patient visit is allowed within 10 days to re-check the HAMD score once a patient reaches 50%.

Patients who relapse may have the following options:
1. alternative ECT pharmacological or psychosocial treatment determined by site PI or designee
2. possible eligibility to enroll in other study protocols and/or
3. patients may decide to seek treatment on their own

7.3 Randomization

Each responder to open-label reboxetine on Day 57 will be entered into the double-blind portion of the study . This will be done by the investigator consecutively assigning a coded double-blind treatment to each subject.

Recognizing that not all patients entering Part 1 will be randomized, a post-randomization patient number will be assigned for each patient randomized in order to accurately separate clinical supplies in the post-randomization phase from the open-label phase. For each randomized patient, the Part 1 patient number and Part 2 patient number will be linked in order that all information from each treatment phase is available. All treatments will be prepared by Pharmacia & Upjohn Inc and labeled with the corresponding patient number.

7.4 Blinding

All patients entered into Part 1 will be treated with open-label reboxetine in an unblinded fashion. On Day 57, a response determination will be made for each patient. Reboxetine nonresponders will be withdrawn from the study. Reboxetine responders will be randomized into Part 2 in a double-blind fashion on Day 57 to continue reboxetine or begin placebo. This part of the study will be conducted in a double-blind fashion in order to minimize potential bias in the evaluation of clinical response and safety.

7.5 Treatment/ Randomization Codes

For Part 2, the investigator will be given sealed codes containing the information on each patient's treatment. Unblinding is restricted to emergency situations and should only be used under circumstances where knowledge of the treatment is necessary for the proper handling of the subject. If the treatment blind is broken, the reason and the date should be recorded and signed by the investigator. The investigator will immediately (within 24 hours) inform the study monitor and will report a full description of reasons for opening the code in the CRF. After breaking the code the patient will be dropped from the trial.

The sealed codes will be returned to the sponsor at the end of the study.

7.6 Prior and Concomitant Therapy

Fluoxetine treatment will be discontinued when reboxetine treatment begins. No concomitant psychotropic medication other than temazepam or zolpidem tartrate as a hypnotic on a p.r.n. basis (e.g. temazepam 7.5-30 mg or zolpidem tartrate 5-10 mg po QHS prn during the study) are allowed. The administration of other concomitant psychotropic drug will be considered a protocol violation and the patient must be excluded from the study.

Other therapy considered necessary for the patient's welfare may be given at the discretion of the Investigator. All such therapy must be recorded in the Case Report Form. No other investigational drug may be used concomitantly with the study drug. Patients are not allowed to participate concurrently in any other clinical drug study. Women of childbearing potential must use an effective means of contraception while on study. Over the counter (OTC) medications are allowed on a p.r.n. basis as symptomatic treatment. They should be recorded along with other medications in the noninvestigational medication case report forms.

7.7 Treatment Compliance

Open-label reboxetine treatment will be administered for 8 weeks and post-randomization treatment will be given for up to an additional 24 weeks. Patient compliance should be strictly monitored. We will provide dosing diaries to the patient for daily recording of drug administration. The investigator's staff will check for regular consumption of experimental treatment. Diaries are source documents that will be retained by the investigator.

The investigator will be responsible for drug accountability. He or she will keep a record of the test medications received from the sponsor as well as a record of the medications dispensed and returned. Discrepancies between dispensed and returned study medication should be explained and recorded.

Medication will be dispensed to the patient on the occasion of each visit. On the same occasion, the bottles of the previous supply will be returned by the patient.

All unused medication and empty bottles will be returned to the sponsor at the end of the study.

8.0 ASSESSMENT OF EFFICACY AND SAFETY

The clinical efficacy will be evaluated by standardized rating scales measuring the severity of several different aspects of the depressive symptomatology. The Hamilton Depression Rating Scale (HAMD) is an observer rating scale intended to assess the state of the patient's condition at the time of the interview and over the preceding few days. The HAMD has been used in a wide variety of populations, is both valid and reliable and has therefore become accepted internationally as a standard measure in psychiatric research of the severity of depression. The 25-item HAMD is the primary measure of efficacy. In addition the 28-item HAMD will be analyzed. The following scales are secondary measures of efficacy. The Montgomery-Asberg Depression Rating Scale (MADRS) is a newer rating scale than the HAMD. It has also been used successfully to assess the severity of depression. In antidepressant and ECT trials the MADRS has been shown to be sensitive to changes in patient symptoms. The Clinical Global Impression consists of three parts (Severity of Illness, Global Improvement and Efficacy Index) which the clinician fills out. It is routinely used as an outcome measure in therapeutic trials. Patient Global Impression is a single item scale in which the patient rates on a 0-10 scale the worsening, stability or improvement in his/her general condition at that time compared with the start of the study. One quality of life scale and one scale exploring social functioning will be used. These scales are the Medical Outcomes Study SF36 (SF36) and Social Adaptation Self-evaluation Scale (SASS) . Symptoms will be assessed by using the patient-rated Kellner Symptom Questionnaire (KSQ). Change in each subject's condition will be monitored by clinical determination of multiaxial diagnosis at the start of the study, and at the end of Parts 1 and 2. Sexual function will be measured using the Rush Sexual Inventory (RSI) Scale.

8.1 Clinical Efficacy/ Safety Assessment

All Clinical Efficacy Assessments should be done by the Investigator/ Co-investigator or personnel suitably trained, delegated by the main Investigator. Every effort should be made to have all psychiatric evaluations and ratings carried out by the same observer for a given patient, preferably in the same setting and at the same time of the day.

8.1.1 Clinical Efficacy Assessments

Clinical efficacy will be evaluated using the Hamilton Depression Rating Scale measuring the severity of the depressive symptomatology at screening, baseline (Day 1) prior to open-

label reboxetine ingestion and on follow-up visit week 1 (Day 8), weeks 2, 3, 4, 5, 6, 7 and 8 (Day 57). Patients entering the post-randomization phase will continue evaluation (for as long as they remain on study) on weeks 9, 10, 11, 12, 13, 14, 15, 16, 20, 24, 28, and 32. Clinical efficacy will also be evaluated using other standardized rating scales listed below, which measure the severity of the depressive symptomatology, quality of life, social adaptation and sexual function. Evaluation with the instruments below will be done at baseline (Day 1) prior to open-label reboxetine ingestion and on follow-up visit week 1 (Day 8), weeks 2, 4, 6, and 8 (Day 57). Patients entering the post-randomization phase will continue evaluation (for as long as they remain on study) on weeks 10, 12, 14, 16, 20, 24, 28, and 32. The Rush Sexual Inventory (RSI) will be administered at baseline (Day 1) prior to open-label reboxetine ingestion and on week 4 and 8 (Day 57). Patients entering the post-randomization phase will take the RSI evaluation on week 16 and 32.

- Montgomery-Asberg Depression Rating Scale (MADRS).

- Clinical Global Impression (CGI).

- Patient Global Impression (PGI).

- Medical Outcomes Study SF36 (SF36).

- Social Adaptation Self-evaluation Scale (SASS).

- Kellner Symptom Questionnaire (KSQ)

- Rush Sexual Inventory (RSI) Scale.

The clinical efficacy assessments are described below:

-Hamilton Depression Rating Scale (17, 25, & 28-item HAMD; See Appendix 7) [18,46,49]: This is the standard scale used for rating severity of depression. It is a clinician rated scale based on of results of a patient interview. The individual items on the HAMD are rated according to their severity either on a 0-2 or 0-4 point scale. The rating by the clinician is completed as a result of the clinician review.

-Montgomery Asberg Depression Rating Scale (MADRS) [19] is also based on a clinical interview. The MADRS has been shown to distinguish satisfactorily between five grades of depression, and its overall performance was found to be equal to the HAMD. Its consists of 10 items, with each item scored on a 7-point scale, graded 0-6. A score of 0 signifies absence of the symptom in question, while a score a score of 6 signifies the most extreme form. Total score ranges from 0-60.

-Clinical Global Impression (CGI) [20] consists of three parts (Severity of Illness, Global Improvement and Efficacy Index) which the clinician fills out. The Severity of Illness and Global Improvement parts are 7-point measures. The Efficacy Index calls for an

estimation of therapeutic effect in relation to severity of side effects based on a 16 point scale. The Global Improvement portion and Efficacy Index refer to changes since admission to the study. For this reason, there are no values assigned to these portions at the Day 1 visit. The CGI scoring is similar to that found in most other scales, in that lower scores indicate better health.

-Patient Global Impression (PGI) is a single item scale in which the patient rates on a 0-10 scale the worsening, stability or improvement in his/her general condition at that time compared with the start of the study.

-Medical Outcomes Study SF36 [21,22]: The SF-36 is a general quality of life scale composed of eight subscales each tapping a different dimension. Each subscale is scored separately; no composite total is calculated. There are several reasons for including this scale. Its reliability and validity are very well established. General population norms exist on thousands of individuals and can be broken out for age and sex comparisons with almost any population sample. This instrument also has been used extensively in patients with clinical depression. Based on these data the scales on role-physical and role-emotional functioning as well as the mental heath scale would be expected to show significant effects with the present study sample size. The SF-36 contains 36 items, is self-administered, and should take less than 20 minutes to complete.

- The Social Adaptation Self-evaluation Scale (SASS)[23]: The Social Adaptation Self-evaluation Scale (SASS) is a 21-question self-evaluation questionnaire which explores the realm of work and leisure, relationships and patient perception of his/her ability to manage the environment. The scale was validated in a survey of the data from the general population in 4000 individuals and sensitivity to change was evaluated in 549 depressed patients enrolled in clinical studies comparing reboxetine with placebo and/or fluoxetine [22]. Answers to each item are scored from 0 to 3 (the higher the better social functioning is). Normality ranges between 35 and 52 points (corresponding to 80% of the general population). In light of its simplicity of use the scale represents an useful tool for the evaluation of social functioning in depression; in addition it might contribute to differentiate the effects of different classes of antidepressant agents (serotonergic regulating mood; noradrenergic sustaining drive) whereas syndromic clinical rating scales fail to do so. The SASS should take less than 15 minutes to complete.

-The Kellner Symptom Questionnaire (KSQ) [47]: The Kellner Symptom Questionnaire is a 92-item, self-rated simple questionnaire which contains state scales of depression, anxiety, anger-hostility and somatic symptoms. In addition, four well-being subscales (contented, relaxed, friendly, and somatic well-being) are included. The four state scales are scored separately; a total score is also calculated. The depression cluster has shown good agreement with the Hamilton Rating Scale for Depression. Because of its simplicity, completion to the scale should take 5 to 10 minutes.

-The Rush Sexual Inventory (RSI) scale [24] is a comprehensive, succinct, self-rated patient inventory created to assess changes in sexual function over time. Each inventory

consists of five visual analogue items and individual "yes/no" gender-separated items. The Day 1 version of the scale includes queries for premorbid as well as current functioning. The follow-up version will be administered according to the study flowchart. Completion time for the patient averages 7 minutes.

-For reasons of safety and as a tertiary indicator of efficacy, the "clinical" DSM-IV 5-Axis diagnosis of each subject during the trial will be followed. This diagnosis will be made within one week of the screening and at the end of parts 1 and 2 (when applicable), and will be based on a clinical, and not a structured, interview. If the subject was seen in a treatment setting prior to study screening, and a multiaxial diagnosis was made, this can be recorded (as long a the one week condition is fulfilled). If the diagnosis was made more than one week earlier, then an abbreviated interview may be done at the time of screening (at the discretion of the primary investigator at each site) to record this diagnosis prior to the start of the study.

Every effort should be made to have all psychiatric evaluations and ratings carried out by the same observer for a given patient, preferably in the same setting and at the same time of the day.

8.1.2 Clinical Safety Assessments:

The following clinical safety assessments will be carried out:

1. Standard medical history: at screening.
2. Standard clinical and physical examination: at screening. (optional PE at study end to be recorded in source document only)
3. Blood pressure and pulse will be measured with the patient rested and in the sitting position at approximately the same time of day at screening, at Day 1 and at each subsequent visit (see flow-chart Appendix 2).
4. Adverse events occurring from Day 1 until the last visit will be recorded. Note that after open-label reboxetine treatment ends on Day 57, follow-up visits at regular intervals will be performed for all patients continuing on study (i.e. for both patients continuing on reboxetine and for those randomized to placebo). In the placebo group these follow-up visits will assess any adverse events that may be associated with drug withdrawal.
5. 12-lead ECG including determination of QT_c interval.
6. Confirm DSM-IV MDD by SCID (version of SCID will be specified in CRF)
7. 5-Axis DSM-IV clinical diagnosis at screening, week 8 and week 32.
8. MGH Scale _____ at screening.

8.2 Laboratory Efficacy/ Safety Assessment

8.2.1 Laboratory Safety Assessments

ECG and laboratory tests (see Appendix 3) will be carried according to the schedule in Appendix 2 Study Flow Chart. Screening must take place in the 2 weeks preceding Day 1. Laboratory tests will be performed at a central laboratory.

ECG will be performed at screening, week 4 and week 8 . Patients entering the post-randomization phase will have ECG performed on week 32 or at the final visit if it occurs prior to week 32. Analysis will include assessment of abnormal ECG patterns and measurement of appropriate intervals (i.e. Heart Rate, PR Interval, QRS Interval, QT Interval and QT_c Intervals).

Serum chemistries, hematology, and urinalysis (see Appendix 3) will be performed at screening, week 4 and week 8. Patients entering the post-randomization phase will have serum chemistries, hematology, and urinalysis performed on week 32 or at the final visit if it occurs prior to week 32.

Serum pregnancy tests (for women of childbearing potential) and urine drug screens (see Appendix 3) will be performed at screening and week 8 . Patients entering Part 2 will have serum pregnancy test and urine drug screen performed on week 32.

For any patient who withdraws between Day 1-57 (weeks 1-8), all tests and forms listed for the Day 57 should be completed. For any patient who withdraws between Day 58-225 (weeks 9-32), all tests and forms listed for the Day 225 (week 32) visit should be completed.

8.3 Procedure for Eliciting Reports of, and Recording and Reporting Adverse Events

Definition
An adverse event (AE) is any untoward medical occurrence in a patient or trial subject administered a drug or biologic (medical product) or using a medical device; the event does not necessarily have a casual relationship with that treatment or usage.

Adverse events include the following:

a. All suspected adverse medication reactions.

b. All reactions from medication overdose, abuse, withdrawal, sensitivity, or toxicity.

c. Apparently unrelated illnesses, including the worsening of a pre-existing illness (see Pre-existing Conditions, below).

d. Injury or accidents. Note that if a medical condition is known to have caused the injury or accident (e.g., a fall secondary to dizziness), the medical condition (dizziness) and the accident (fall) should be reported as two separate adverse events. The outcome of the accident (e.g., hip fracture secondary to the fall) should be recorded under Comments.

e. Abnormalities in physiological testing or physical examination findings that require clinical intervention or further investigation (beyond ordering a repeat [confirmatory] test).

f. Laboratory abnormalities that require clinical intervention or further investigation [beyond ordering a repeat (confirmatory) test] unless they are associated with an already reported clinical event. Laboratory abnormalities associated with a clinical event (e.g., elevated liver enzymes in a patient with jaundice) should be described under Comments on the report of the clinical event rather than listed as a separate adverse event.

Pre-existing Conditions

In this study, a preexisting condition (i.e., a disorder or symptom present before the adverse event reporting period started and noted on the pretreatment medical history/physical form or Day 1 adverse event form) should not be reported as an adverse event unless the condition worsens or episodes increase in frequency during the adverse event reporting period (see also Symptoms of Depression).

Procedures

Diagnostic and therapeutic non-invasive and invasive procedures, such as surgery, should not be reported as adverse events. However, the medical condition for which the procedure was performed should be reported if it meets the definition of adverse event. For example, an acute appendicitis that begins during the adverse event reporting period should be reported as the adverse event and the resulting appendectomy noted under Comments.

Symptoms of Depression

With the exception of worsening of depressed mood, worsening of symptoms of depression are to be considered as adverse events in this protocol. Any increase in the intensity of depressed mood should be reflected on the Hamilton Rating Scale for Depression (Item 1). However, increases in the intensity of other symptoms of depression (e.g., sleep difficulties, somatic symptoms, genital symptoms, weight change, anxiety, other psychiatric symptoms) will be considered as an Adverse Event. It is recognized that such symptoms may be present prior to the start of study drug (i.e., at Day 1). Only those

symptoms whose intensity increases during the treatment period will be counted as an Adverse Event.

Adverse Event Reporting Period

The adverse event reporting period for this study begins at the time of the Day 1 evaluation and ends at the final clinic visit (week 32; Day 225). Treatment Emergent Symptoms will be considered only those occurring within the treatment period (Day 1 until Day 225). A disorder or symptom present before the adverse event reporting period started and noted on the pretreatment medical history/physical form or Day 1 adverse event form should not be reported as an adverse event unless the condition worsens or episodes increase in frequency during the adverse event reporting period (Day 1-225).

All adverse events that occur in study subjects during this reporting period must be reported to Pharmacia & Upjohn, WHETHER OR NOT THE EVENT IS CONSIDERED MEDICATION RELATED. In addition, any known untoward event that occurs subsequent to the adverse event reporting period that the investigator assesses as possibly related to the investigational medication should also be reported as an adverse event.

Seriousness (Gravity)

Each adverse event is to be classified by the investigator as SERIOUS or NONSERIOUS. This classification of the gravity of the event determines the reporting procedures to be followed.

An adverse event that meets one or more of the following criteria/outcomes is classified as SERIOUS:

- Death
- Life-threatening (i.e., at immediate risk of death)
- In-patient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- Any other adverse event that the investigator or company judges to be serious or which is defined as serious by the regulatory agency in the country in which the adverse event occurred.

Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject or may require medical or surgical intervention to prevent one of the outcomes listed above.

Eliciting Adverse Event Information

The investigator is to report all directly observed adverse events and all adverse events spontaneously reported by the trial subject using concise medical terminology. In addition, each trial subject will be questioned about adverse events at Day 1 and at each clinic visit following initiation of treatment The question asked will be “Since your last clinic visit have you had any health problems?"

Reporting

If a SERIOUS adverse event occurs, the Pharmacia & Upjohn monitor is to be notified using the designated form within 24 hours of awareness of the event by the investigator. The initial report is to be followed by submission of more detailed adverse event information within 5 working days of the event. If unexpected, serious adverse events are also to be reported immediately to the responsible institutional review board. Please review the table below.

Serious adverse events should also be reported on the clinical trial adverse event case report form.

Note: The form for collection of SAE information is not the same as the adverse event case report form. Where the same data is collected, the forms must be completed in a consistent manner. For example, the same adverse event term should be used on both forms.

NONSERIOUS adverse events are to be reported on the adverse event case report forms, which are to be submitted to Pharmacia and Upjohn as specified in the adverse event report submission procedure for this protocol.

REPORTING REQUIREMENTS FOR ADVERSE EVENTS

Gravity	Reporting Time	Type of Report
SERIOUS	Within 24 hours	Initial report on designated SAE form
	Within 5 working Days	Final report on designated SAE form
NONSERIOUS	Per case report form	Appropriate case report forms submission procedure

NOTE: In the rare event that the investigator does not become aware of the occurrence of a serious adverse event immediately (for example, if an outpatient trial subject initially seeks treatment elsewhere), the investigator is to report the event within 24 hours after learning of it and document his/her first awareness of the adverse event.

Recording Instructions

Adverse events are to be recorded in the case report forms as specified.

If required on the adverse event case report forms, the investigator will use the adjectives MILD, MODERATE, or SEVERE to describe the maximum intensity of the adverse event. For purposes of consistency, these intensity grades are defined as follows:

MILD	Does not interfere with subject's usual function
MODERATE	Interferes to some extent with subject's usual function
SEVERE	Interferes significantly with subject's usual function

Note the distinction between the gravity and the intensity of an adverse event. **Severe** is a measure of intensity; thus, a **severe** reaction is not necessarily a **serious** reaction. For example, a headache may be severe in intensity, but would not be classified as serious unless it met one of the criteria for serious events listed above.

The investigator will also be asked to assess the possible relationship between the adverse event and the investigation medication as well as any concomitant medications.

Follow-up of Unresolved Events

All adverse events should be followed until they are resolved or the subject's participation in the trial ends (i.e., until a final report is completed for that subject). Instructions for reporting changes in an ongoing adverse event during a subject's participation in the trial are provided in the instructions that accompany the adverse event case report forms.

In addition, all serious adverse events and those nonserious events assessed by the investigator as possibly related to the investigation medication should continue to be followed even after the subject's participation in the trial is over. Such events should be followed until they resolve or until the investigator assesses them as "chronic" or "stable." Resolution of such events are to be documented on the appropriate CRF.

Exposure *in utero*

If pregnancy is discovered during the treatment period, study medication should immediately be discontinued. If any trial subject becomes or is found to be pregnant while receiving investigational medication or within 30 days of discontinuing investigational medication, the investigator is to submit an adverse event case report form that includes the anticipated date of birth or pregnancy termination. The subject is then to be followed by the investigator until completion of the pregnancy. If the pregnancy ends for any reason before the anticipated date provided, the investigator should notify the Pharmacia & Upjohn monitor.

If the outcome of the pregnancy meets the criteria for immediate classification as a serious adverse event (ie, spontaneous abortion, stillbirth, neonatal death, or congenital anomaly, including that in an aborted fetus), the investigator should follow the procedures for reporting serious adverse events; ie, report the event to the principal monitor within 24 hours and follow up by submission of appropriate adverse event case report forms.

Additional information about pregnancy outcomes that are classified as serious adverse events follows:

- Note that "spontaneous abortion" includes miscarriage and missed abortion.

- All neonatal deaths that occur within one month of birth should be reported, without regard to causality, as serious adverse events. In addition, any infant death after one month that the investigator assesses as possibly related to the in utero exposure to the study medication should also be reported.

- In the case of a live birth, the "normality" of the newborn can be assessed at time of birth (ie, there is no required minimum follow-up of a presumably normal infant before the Exposure in Utero form can be completed).

- The "normality" of an aborted fetus can be assessed by gross visual inspection unless there are preabortion laboratory findings suggestive of a congenital anomaly.

9.0 STATISTICS

9.1 Statistical Analysis Plan

Statistical Method

The intent-to-treat (ITT) data set which includes all patients who were randomized into the trial and received at least one treatment dose and with at least one post baseline efficacy follow up will be used for analysis. Two types of analyses will be performed for the primary variables: “last observation carried forward” (LOCF) and “observed cases” (OC). The LOCF analysis uses the last valid assessment as an estimate for all subsequent missing values. The OC analysis does not replace the missing values.

Continuous variables such as the age and HAMD totals will be summarized in tables of means, standard deviations etc. by visit. The one-way analysis of variance model will be used to test for treatment difference. As there will be very few evaluable patients per treatment group in each center, effect of center and treatment by center interaction will not be investigated in the statistical analysis.

Categorical variables such as sex and relapse rate will be summarized in tables of counts and percentages. Treatment group difference will be tested using the chi-squared test or the Fisher's Exact test.

Time to relapse and time to remission will be estimated using the Kaplan-Meier survival function, and the difference between the treatment groups tested with the log-rank test.

All of the statistical tests are two-sided and the treatment group difference will be considered significant if the p-values are less than or equal to 0.05.

Baseline and Demographic Measures

As there are two phases in this study - the open label phase and the double-blind phase, demographic measures and baseline characteristics (e.g. sex, age, pretreatment condition) will be summarized 1) for patients enrolled into the open label phase; and 2) for patients randomized into the double blind phase. Comparability of patients randomized into the two treatment groups will be assessed.

Efficacy Measures

Open Label Reboxetine Treatment Phase -

The number and percentage of patients who respond (at least 50% decrease in HAMD score compared to Day 1 and CGI improvement of 1 or 2) to reboxetine at the end of the open label phase will be calculated. This analysis will be based on the patients enrolled into the study and who are evaluable during this part of the study.

Post Randomization Treatment Phase -

Comparison between treatments will be mainly based on the primary efficacy measure of the proportion of patients experiencing at least one relapse in the treatment period following randomization. Relapse of MDD is defined as a $\geq$ 50% increase in the 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD

total score of ≥ 10 (on the 25-item HAMD). Any patient withdrawing for any reason will be classified as to whether they had relapsed during this period.

Time to relapse, which is defined as the number of days between the randomization date and the date when the patient is first classified as "relapse", will be analyzed using the Kaplan-Meier survival function; and comparison between treatments will be tested by the log-rank test.

Remission rate, which is the percentage of patients with a total 25-item HAMD score of <7 or less at the last assessment, and time to remission since Day 57, will be compared between treatments.

Other supporting efficacy measures are the scores on the following scales and some of their components (described in section 8.1.1): 28-item HAMD, 17-item HAMD, DSM-IV 5-Axis, MADRS, CGI, PGI, SASS, KSQ, SF36 and RSI. These scores will be summarized by treatment and visit. The change of the scores at the last assessment from baseline (Day 57 randomization) will be compared between treatments.

An evaluation between the last Part I visit and the first Part 2 visit will be done to identify any treatment emergent symptoms.

Correlational analysis will be used to examine the relationship between the clinical variables and the quality of life and social adaptation variables.

Analysis of efficacy measures will be conducted on patients randomized into the double blind phase of the study, who have taken at least one dose of study medication and have at least one assessment after randomization.

Exploratory analyses will be conducted to examine patient characteristics in relation to their responses to reboxetine, and to identify, if possible, the patients who respond to reboxetine but not fluoxetine.

Safety Measures

All patients who are enrolled and have received at least one dose of the study drug will be included in the safety analyses.

Adverse Events

Analysis of adverse events will be focused on treatment emergent symptoms (TES), which are the symptoms and signs not present at Day 1 that appear during treatment, or if present at Day 1, that become more severe during treatment. The TES will be summarized (1) by body system and COSTART term, (2) by maximum intensity, (3) by relation to the drug, (4) by seriousness, (5) by gender, and (6) by age. A summary of adverse events causing

termination of study medication will also be presented. Patients with serious adverse events and dropouts due to adverse events will be listed.

Vital Signs

Vital signs will be summarized by treatment and visit. For each vital sign, the paired t-test will be used to determine at each visit if the change of the response at that visit is significantly different from baseline. Patients showing clinically significant changes in vital signs during treatment will be listed.

ECG and Laboratory Data

ECG (including QT_c intervals) and lab test results will be summarized in frequency tables showing normal/abnormal findings by visit. Changes from baseline will be shown by cross-tabulating the last assessment responses with Day 1 responses. Patients with abnormal test results will be listed.

9.2 Determination of Sample Size

Sample size was calculated based on the assumption that at least 50% of the patients who discontinue treatment will experience a relapse within 6 months compared to 20% of the patients who continue on active medication. This was based on results of a previous study on reboxetine (protocol 20124/013) and published papers [38,44,45]. At significance level of 0.05 (2-tailed), power level 0.8, the number of patients required to detect a 30% difference in relapse rate is 78 (39 per treatment arm). Assuming that 10% of the patients randomized into the double blind phase will be non-evaluable for efficacy, 87 patients will be required for randomization at Day 57 of the study. It was estimated that about 200 patients will be needed for the open label phase to get enough patients for randomization.

10 QUALITY CONTROL (QC) AND QUALITY ASSURANCE (QA)

Monitoring visits to the trial site will be made periodically during the trial, to ensure that all aspects of the protocol are followed. Source documents will be reviewed for verification of agreement with data on case report forms. The investigator/institution guarantee access to source documents by Pharmacia & Upjohn and appropriate regulatory agencies.

The trial site may also be subject to quality assurance audit by Pharmacia & Upjohn as well as inspection by appropriate regulatory agencies.

It is important that the investigator and their relevant personnel are available during the monitoring visits and possible audits and that sufficient time is devoted to the process.

11 STOPPING RULES / DISCONTINUATION CRITERIA

Pharmacia and Upjohn reserve the right to discontinue the trial prior to inclusion of the intended number of subjects, but intends only to exercise this right for valid scientific or administrative reasons. After such a decision, the investigator must contact all actively participating subjects.

12.0 ETHICS

12.1 Ethical Conduct of the Study

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th world medical assembly, Helsinki, Finland, 1964 and later revisions (Venice and Hong Kong revisions).

12.2 Institutional Review Boards

It is the responsibility of the investigator to obtain approval of the trial protocol/amendments from the IRB. All correspondence with the IRB should be filed by the investigator. Copies of IRB approvals should be forwarded to Pharmacia & Upjohn.

12.3 Subject Information and Consent

It is responsibility of the investigator to give each subject (or the subject's representative) prior to inclusion in the trial, full and adequate verbal and written information regarding the objective and procedures of the trial and the possible risks involved. The subjects must be informed about their right to withdraw from the trial at any time. Written subject information must be given to each subject before enrollment. The written subject information must not be changed from the provided sample informed consent without prior discussion with Pharmacia & Upjohn. Furthermore, it is the responsibility of the investigator to obtain signed and dated consent from all subjects prior to inclusion in the trial. If the date is the same day as enrollment, it is recommended that the time is also recorded by the subject to help ensure that informed consent was, in fact, obtained prior to the subject's participation in study activities.

13.0 DATA HANDLING AND RECORD KEEPING

13.1 Case Report Form

A Case Report Form (CRF) is required and should be completed for each included subject. The CRF is designed by Pharmacia & Upjohn and presented to the investigator. Corrections of data should be made using one single line, leaving the corrected data clearly visible. All changes should be initialed and dated. Correction fluid is not allowed. The completed original CRFs are the sole property of Pharmacia & Upjohn and should not be made available in any form to third parties, except for authorized representatives of the United States Food and Drug Administration (FDA), without written permission of Pharmacia & Upjohn.

13.2 Record Retention

To enable any further evaluations and/or audits from FDA/Pharmacia & Upjohn, the Investigator agrees to keep records, including the identify of all participating subjects (sufficient information to link records e.g., CRF and subject records), all original signed Informed Consent Forms, copies of all CRFs and detailed records of drug disposition. To comply with International regulations, the records should be retained by the Investigator for 15 years.

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APPENDIX 1

DSM-IV Criteria for Major Depressive Episode

A. Five (or more) of the following symptoms have been present during the same 2-week period and represent a change from a previous functioning; at least one of the symptoms is either (1) depressed mood or (2) loss of interest or pleasure.

NOTE: Do not include symptoms that are clearly due to a general medical condition, or mood-incongruent delusions or hallucinations.

(1) depressed mood most of the Day, nearly every day, as indicated by either subjective report (e.g., feels sad or empty) or observation made by others (e.g., appears tearful).
(2) markedly diminished interest or pleasure in all, or almost all, activities most of the day, nearly every day (as indicated by either subjective account or observation made by others)
(3) significant weight loss when not dieting or weight gain (e.g., a change of more than 5% of body weight in a month), or decrease or increase in appetite nearly every day.
(4) insomnia or hypersomnia nearly every day
(5) psychomotor agitation or retardation nearly every day (observable by others, not merely subjective feels of restlessness or being slowed down)
(6) fatigue or loss of energy nearly every day
(7) feelings of worthlessness or excessive or inappropriate guilt (which may be delusional) nearly every day (not merely self-reproach or guilt about being sick)
(8) diminished ability to think or concentrate, or indecisiveness, nearly every day (either by subjective account or as observed by others)
(9) recurrent thoughts of death (not just fear of dying), recurrent suicidal ideation without a specific plan, or a suicide attempt or a specific plan for committing suicide.

B. The symptoms do not meet criteria for a Mixed Episode.

C. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning.

D. The symptoms are not due to the direct physiological effects of a substance (e.g., a drug of abuse, a medication) or a general medical condition (e.g., hypothyroidism).

E. The symptoms are not better accounted for by Bereavement, i.e., after the loss of a loved one, the symptoms persist for longer than 2 months or are characterized by marked functional impairment, morbid preoccupation with worthlessness, suicidal ideation, psychotic symptoms or psychomotor retardation.

Diagnostic criteria for Major Depressive Disorder, Single Episode

A. Presence of a single Major Depressive Episode.

B. The Major Depressive Episode is not better accounted for by Schizoaffective Disorder and is not superimposed on Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder Not Otherwise Specified.

C. There has never been a Manic Episode, a Mixed Episode, or a Hypomanic Episode.
Note: This exclusion does not apply if all of the manic-like, mixed-like, or hypomanic-like episodes are substance or treatment induced or are due to the direct physiological effects of a general medical condition.

Specify (for current or most recent episode):
Severity/Psychotic/Remission Specifiers
Chronic
With Catatonic Features
With Melancholic Features
With Atypical Features
With Postpartum Onset

Diagnostic criteria for Major Depressive Disorder, Recurrent

A. Presence of two or more Major Depressive Episodes.
Note: To be considered separate episodes, there must be an interval of at least 2 consecutive months in which criteria are not met for a Major Depressive Episode.

B. The Major Depressive Episodes are not better accounted for by Schizoaffective Disorder and are not superimposed on Schizophrenia, Schizophreniform Disorder, Delusional Disorder, or Psychotic Disorder Not Otherwise Specified.

C. There has never been a Manic Episode, a Mixed Episode, or a Hypomanic Episode.
Note: This exclusion does not apply if all of the manic-like, mixed-like, or hypomanic-like episodes are substance or treatment induced or are due to the direct physiological effects of a general medical condition.

Specify (for current or most recent episode):
Severity/Psychotic/Remission Specifiers
Chronic
With Catatonic Features
With Melancholic Features
With Atypical Features

With Postpartum Onset

Specify:

Longitudinal course specifiers (with or without interepisode recovery)
With seasonal pattern

APPENDIX 2: STUDY FLOW-CHART (see Key next page)

		PART 1					PART 2		
Day*	Screen**	1	8, 15 and 22	29	36, 43 and 50	57 [1]	58-113	141-197	225[1] (or end of treatment)
Week	Screen**	-	1,2 and 3	4	5,6 and 7	8	9-16 (weekly visits)	20-28 (monthly visits)	32[1] (or final visit)
Confirm DSM- IV MDD (by SCID)[2]	✓								
Sign consent	✓								
Medical history	✓								
DSM-IV 5-Axis Clinical Dx[3]	✓					✓[6]			✓
MGH Antidepressant Tx Resp. Scale	✓								
Physical examination	✓								✓ (optional)
Randomization						✓			
ECG - 12-lead	✓			✓		✓[6]			✓
Serum chemistry[4]	✓			✓		✓[6]			✓
Hematology[4]	✓			✓		✓[6]			✓
Urinalysis[4]	✓			✓		✓[6]			✓
Serum Pregnancy Test[4]	✓					✓[6]			✓
Urine drug screen[4]	✓					✓[6]			✓
Vital signs	✓	✓	✓	✓	✓	✓[6]	✓	✓	✓
25-item HAMD & addendum	✓	✓	✓	✓	✓	✓[6]	✓	✓	✓
Assess for MDD relapse[5]							✓	✓	✓
MADRS, CGI, PGI, SF36, KSQ, SASS		✓	✓ wks 1,2	✓	✓ wk 6	✓[6]	✓ wks 10,12,14, 16	✓	✓
RSI		✓		✓		✓[6]	wk 16		✓
Compliance			✓	✓	✓	✓[6]	✓	✓	✓
Dispensing Med.		✓	✓	✓	✓	✓[6]	✓	✓	✓
Adverse Events		✓	✓	✓	✓	✓[6]	✓	✓	✓

APPENDIX 2: Key

Abbreviations:
DSM-IV = Diagnostic and Statistical Manual of Mental Disorders; Fourth Edition
MDD = Major Depressive Disorder
HAMD = Hamilton Rating Scale for Depression
MADRS = Montgomery Asberg Depression Rating Scale
CGI=Clinical Global Impressions
PGI =Patient Global Impressions
SF36 = Medical Outcome SF36
SASS = Social Adaptation Self-evaluation Scale
KSQ = Kellner Symptom Questionnaire
RSI = Rush Sexual Inventory Scale
SCID = Structured Clincial Interview for DSM-IV Axis I Disorders
wk = week
MGH Antidepressant Tx Resp. scale = Massachusetts General Hospital Antidepressant Treatment Response Questionnaire [50]

* Visits should be targeted to occur $\pm$ 1 day through week 16; thereafter $\pm$ 2 days

** Screening visit must take place within 2 weeks prior to Day 1.

1. For any patient who withdraws between Day 1-57, all tests and forms listed for the Day 57 visit should be completed. For any patient who withdraws between Days 58-225, all tests and forms listed for the Day 225 visit should be completed.

2. Perform the following SCID Modules (Document in source records):
   A = Evaluation of Mood Episode, Dysthymic Disorder, Mood Disorder due to a GMC, and Substance-Induced Mood Disorder.
   B = Psychotic and Associated Symptoms
   C = Psychotic Disorders
   D = Mood Disorders

3. Except for MDD (which is determined by appropriate SCID Modules), the 5-Axis clinicaldiagnosis can be made based on a clinical interview.

4. See Appendix 3

5. See Section 7.2 for definition of MDD relapse.

6. This test must be performed prior to post-randomization dosing.

APPENDIX 3:

REQUIRED LABORATORY DETERMINATIONS

Hematology

Hematocrit
Hemoglobin
White Cell Count
Differential
- Total neutrophils
- Lymphocytes
- Monocytes
- Eosinophils
- Basophils

Platelet count
RBC
MCV

Reticulocyte count

Serum Chemistry

Electrolytes (Na, K, Cl, CO2)
BUN/urea nitrogen
Creatinine
Glucose
Uric Acid
Total Bilirubin
Aspartate Transaminase (SGOT, AST)
Alanine Transaminase (SGPT, ALT)
Alkaline Phosphatase
Thyroid function (TSH and T_4) - Screen only

Urinalysis

Appearance
Color
Specific Gravity
pH
Protein
Ketone
Bilibrubin
Blood

Glucose

Nitrite
Leukocytes
Urobilinogen
Reducing Substance

Pregnancy Test (Serum)

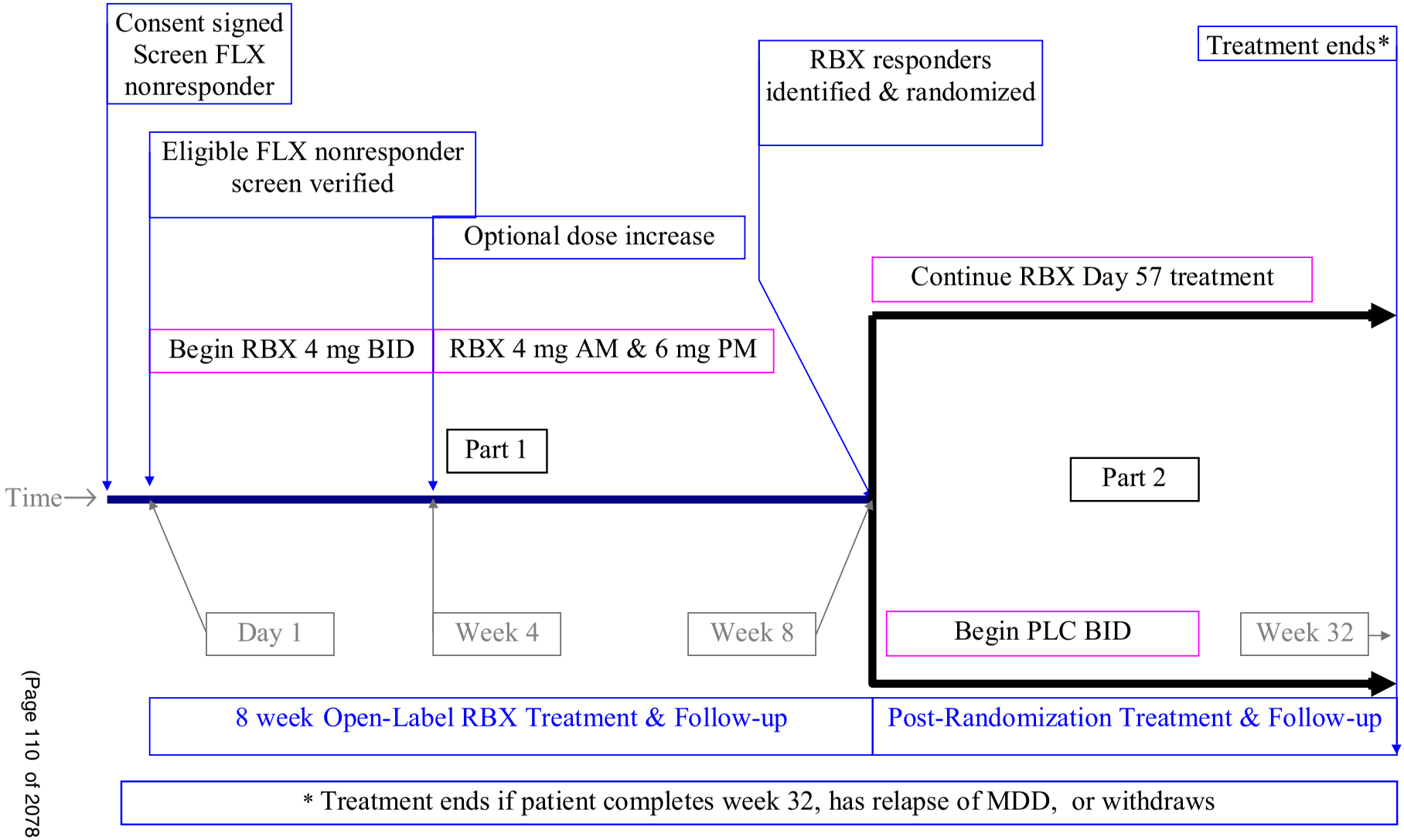
All female patients of childbearing potential; Screen, week 8, and week 32
(Not necessary for surgically sterilized or postmenopausal women)

Urine Drug Screen

To be performed at Screen and week 8, and week 32 visits.

sympathomimetic amines
barbiturates
benzodiazepines
marijuana metabolites
cocaine metabolites
methadone
methaqualone
opiates
phencyclidine
propoxyphene

APPENDIX 4: M-2020-0034 STUDY TIMELINE



APPENDIX 5: SUMMARY OF INVESTIGATOR OBLIGATIONS

The following checklist summarizes investigator obligations for this study:

Before the study starts

- Obtain approval from the Pharmacia & Upjohn Inc monitor for any investigator-initiated changes in the supplied proposed consent form.

- Obtain Institutional Review Board (IRB) approval of the protocol, consent form, and any advertisements to be used to recruit study subjects.

- Provide the Pharmacia & Upjohn Inc monitor with documentation of that approval.

- Obtain approval from the Pharmacia & Upjohn Inc monitor for any IRB-requested changes in the consent form. Provide the monitor with a copy of the final consent form.

- Complete a Statement of Investigator form (FDA 1572) and forward it to the Pharmacia & Upjohn monitor.

- List on the 1572 form your name (as investigator) and the names of all subinvestigators associated with the study. Provide a current copy of your curriculum vitae, along with that of all subinvestigators.

- Provide the monitor with information on persons whose participation materially affects the study (ancillary personnel).

- Sign the protocol and the clinical study agreement letter and return them to the sponsor.

During the conduct of the study

- Conduct the study according to the approved protocol. Should any deviation from the protocol become necessary, obtain Pharmacia & Upjohn Inc agreement.

- As required, obtain approval from the IRB for any protocol amendments and for any new or revised advertisements to be used to recruit study subjects.

- As required, modify the consent form to reflect the protocol change. Obtain approval for the revised consent form from the monitor and the IRB.

- Provide the monitor with copies of any progress reports submitted to the IRB and documentation of any IRB approvals for study continuation.

- Using the consent form approved by the IRB and the principal monitor, obtain written informed consent from each subject before the subject is allowed to participate in the study.

- Inform existing study subjects of any significant new findings provided by Pharmacia & Upjohn Inc related to the safety of the investigational medication.

- Provide the subject with a copy of the signed, dated consent form and retain the original in the subject's file.

- Immediately report any serious adverse events to the Pharmacia & Upjohn monitor. Immediately report any unexpected serious adverse events to the IRB. Report nonserious adverse events as specified in the case report submission procedures for this study. (See the ADVERSE EVENTS section of the protocol.)

- Complete and submit all other case report forms to the monitor according to the procedures and submission schedule for this protocol.

- Notify the monitor of any changes in study personnel that occur during the conduct of the study.

<u>After completion of the study</u>

- Inventory and return all unused study medication to Pharmacia & Upjohn Inc. (A monitor will assist you.)

- Notify the IRB when the study is completed (i.e., after the last study visit of the final study subject).

- Submit a final report on the study to the IRB.

- Maintain all study records until disposal is authorized by Pharmacia & Upjohn Inc.

APPENDIX 6: CENTRAL LABORATORY PROCEDURES

See Study Reference Manual for details of sample collection, processing and packaging as well as central laboratory reference ranges.

APPENDIX 7

COMPARISON OF HAMD VERSIONS USED IN THIS STUDY

Item	17 Items	25 Items	28 Item
Depressed mood	x	x	x
Distinct quality of mood		x	
Lack of reactivity		x	
Feelings of guilt	x	x	x
Suicide	x	x	x
Insomnia - early	x	x	x
Insomnia - middle	x	x	x
Insomnia - late	x	x	x
Work and activities	x	x	x
Retardation	x	x	x
Agitation	x	x	x
Anxiety - psychic	x	x	x
Anxiety - somatic	x	x	x
Somatic - gastrointestinal	x		x
Somatic - general	x		x
Genital symptoms	x		x
Hypochondriasis	x	x	x
Loss of weight	x	x	x
Loss of appetite		x	
Insight	x	x	x
Diurnal variation		x	x
Weight gain		x	x
Worthlessness		x	
Helplessness		x	
Hopelessness		x	
Loss of energy		x	
Loss of interest		x	
Loss of libido		x	

COMPARISON OF HAMD VERSIONS USED IN THIS STUDY

Item	17 Items	25 Items	28 Item
Depersonalization/ derealization			x
Paranoid symptoms			x
Obsessive/compulsive			x
Hypersomnia - early bedtime			x
Hypersomnia - oversleeping			x
Hypersomnia - napping			x
Increased appetite			x
Retardation - psychic			x
Retardation - motoric			x

Amendment

1 IDENTIFYING INFORMATION FOR AMENDMENT

Amendment Number:	1
Amendment Date:	18 June 1999
Product:	PNU-155950E (Reboxetine)

2 IDENTIFYING INFORMATION FOR ORIGINAL DOCUMENT

Document Number:	
Document Type:	Study Protocol
Title:	Reboxetine (PNU-155950E) vs Placebo in the Treatment of Major Depressive Disorder Resistant to Fluoxetine
Protocol Number:	M/2020/0034
Project / Product Identifier:	53,206
Author(s) / Study Director:	Saeeduddin Ahmed, MD
Issue / Approval Date:	12 March 1999

3 PREVIOUS AMENDMENTS

None

4 AMENDMENT SUMMARY

4.1 In response to the questions and concerns raised at the Investigator Meeting on May 6th, 1999 and subsequently, several changes have been made to the protocol. These changes and their justifications are contained in section 5. Many of these are corrections and clarifications, but a few require changes in study procedures. The latter are:

- Conversion of the physical examination (PE) at the end of the study from optional to mandatory (for any subject whose study participation ends before Week 32, the PE should be done at the time of withdrawal).
- Allowance of a period up to 72 hours between the time of fluoxetine discontinuation and reboxetine initiation.
- Adding a specific requirement to query for adverse events on Day 1 related to fluoxetine use.
- Exclusion of certain psychoactive food supplements.
- A cautionary note regarding concomitant use of inducers and inhibitors of cytochrome p450-3A4.

For site convenience, a "working" protocol will be distributed, which incorporates all the changes in the amendment.

5 SPECIFIC CHANGES

5.1 Abbreviations and Definitions of Terms, page 6

Reason for change: The official name of the MGH scale was incomplete.

a. Description of Change
From:_____= Mass. General Hospital Scale

To: MGH = Massachusetts General Hospital Antidepressant Treatment Response Questionnaire

5.2 5.2 Overall Trial Design and Plan, page 17

Reason for change: The number of sites was increased from 20 to 30 to shorten the enrollment period.

a. Description of Change

From: This phase IIIb study will be carried out in approximately 20 centers.

To: This phase IIIb study will be carried out in approximately 30 centers.

5.3 6.0 Selection and Withdrawal of Subjects, page 18

Reason for change: The number of sites was increased from 20 to 30 to shorten the enrollment period.

a. Description of Change

From: Each of the approximately 20 centers will be expected to enroll 10 patients within a period of 12 months, for a total of approximately 200 patients per year overall.

To: Each of the approximately 30 centers will be expected to enroll 8 patients within a period of 12 months, for a total of approximately 240 patients overall.

5.4 7.2 Treatment Schedule, page 23

Reason for change: The study medication is in **tablet** form.

a. Description of Change

From: From week 9 to week 32, patients randomized to placebo will receive bottles in which each dose (morning and evening) is a placebo capsule.

To: From week 9 to week 32, patients randomized to placebo will receive bottles in which each dose (morning and evening) is a placebo tablet.

5.5 8.1.2 Clinical Assessments, page 29

Reason for change: To add an additional safety measure and document any changes in the subject's physical condition.

a. Description of Change

From: 2. Standard clinical and physical examination: at screening. (optional PE at study end to be recorded in source document only)

To: 2. Standard clinical and physical examination: at screening and final visit **(for any subject whose study participation ends before week 32, the PE should be done at the time of withdrawal)**.

5.6 8.1.2 Clinical Assessments, page 29

Reason for change: The official name of the MGH scale was incomplete.

a. Description of Change

From: 8. MGH Scale _____at screening.

To: 8. Massachusetts General Hospital Antidepressant Treatment Response Questionnaire at screening.

5.7 Appendix 2: Study Flow-Chart, page 47, under "Physical examination" at Week 32

Reason for change: (To add an additional safety measure and document any changes in the subject's physical condition.)

a. Description of Change

From: ✓ (optional) in the Physical examination row, and the week 32 column.

To: ✓ in the Physical examination row, and the week 32 column.

5.8 5.3 Duration/Schedule of Events, page 17

Reason for change: To allow additional flexibility to sites and investigators, without sacrificing the validity of the study (due to long half-life of fluoxetine).

a. Description of Change

From: Upon entry into this study, each patient will be immediately switched to reboxetine without an intervening washout period and will begin treatment with reboxetine 8 mg/day (4 mg BID) on Day 1.

To: Upon entry into this study, each subject will begin treatment with reboxetine 8 mg/day (4 mg BID) on Day 1. Reboxetine should not be started on the same day as the last dose of fluoxetine, and not more than 72 hours later.

5.9 7.6 Prior and Concomitant Therapy, page 24

Reason for change: To allow additional flexibility to sites and investigators, without sacrificing the validity of the study (due to long half-life of fluoxetine).

a. Description of Change

From: Fluoxetine treatment will be discontinued when reboxetine treatment begins.

To: Fluoxetine treatment will be discontinued no more than 72 hours before starting reboxetine treatment. Reboxetine should not be started on the same day as the last dose of fluoxetine.

5.10 8.3 Procedure for Eliciting Reports of, and Recording and Reporting Adverse Events, "Eliciting Adverse Event Information" section, page 32

Reason for change: To capture side-effects that may be attributable to Prozac and are present on Day 1.

a. Description of Change

From: The question asked will be "Since your last clinic visit have you had any health problems?" (Standard Adverse Event query)

To: The Standard Adverse Event query "Since your last clinic visit have you had any health problems?" will be used throughout the study. On Day 1 an additional question will be asked to solicit information about possible health problems related to Prozac. The recommended additional Day 1 query is “Have you noticed any health problems, which are still present, while you have been taking Prozac?”.

5.11 7.6 Prior and Concomitant Therapy, page 24

Reason for change: No concomitant psychotropic medications are allowed in this study. Certain supplements have psychoactive properties, thus are not to be used while participating in this study. Cytochrome p450-3A4 plays a part in the metabolism of reboxetine. Thus, medications classed as inducers and inhibitors of this enzyme need to be carefully monitored during study participation.

a. Description of Change

From: The administration of other concomitant psychotropic drug will be considered a protocol violation and the patient must be excluded from the study.

To: The administration of other concomitant psychotropic drug will be considered a protocol violation and the patient must be excluded from the study. Food supplements with prominent central nervous system effects, such as St. John's Wort, kava kava, Ginseng, and melatonin are not allowed in the study.

Caution should be exercised in enrolling subjects who are taking drugs that are potent inducers or inhibitors of cytochrome p450 3A4 (see Appendix 8).

6 APPROVAL

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Signature Date

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PROTOCOL M/2020/0034

PART 1: DATAFAX VISIT MAP

Schedule of CRF Pages to be Completed at Each Patient Assessment

Plate No.	Form Title	Study Period	Screen	Day 1 (Week 0)	Scheduled Visits								End of Part 1
					End of Week								
					1	2	3	4	5	6	7	8	
		Seq. #	0	1	101	102	103	104	105	106	107	108	199
1-3	Eligibility Checklist (3 pages)		1-3										
4	Medical History		4										
5	Physical Examination		5										
6	Demographic / Vital Signs / Pregnancy Test / ECG		6										
7	Social / Occupational Status		7										
8	Psychiatric History		8										
9	Diagnosis of Depression / Expectation of Subject		9										
10	DSM-IV 5-Axis Clinical Diagnosis		10									158	
11-12	MGH: Antidepressant Treatment Response Questionnaire (2 pages)		11-12										
13-14	History of Other Psychoactive Drugs (2 pages)		13-14										
15-18	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) (4 pages)		15-18	21-24	43-46	61-64	79-82	86-89	107-110	113-116	131-134	138-141	
19	Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)*		19	25	47	65	83	90	111	117	135	142	
20	Vital Signs / AE & Concomitant Mediaction / Study Medication (Day 1)			20									
21	Vital Signs / AE & Concomitant Mediaction / Study Medication				42	60	78	84	106	112	130	136	
22-24	Montgomery-Asberg Depression Rating Scale (MADRS) (3 pages)			26-28	48-50	66-68		91-93		118-120		143-145	
25	Clinical Global Impressions (CGI)			29	51	69		94		121		146	
26	Patient Global Impressions (PGI)			30	52	70		95		122		147	
27-29	SF-36 Health Survey (3 pages)			31-33	53-55	71-73		96-98		123-125		148-150	
30-31	Kellner Symptoms Questionnaire (KSQ) (2 pages)			34-35	56-57	74-75		99-100		126-127		151-152	
32-33	Social Adaptation Self-evaluation Scale (SASS) (2 pages)			36-37	58-59	76-77		101-102		128-129		153-154	
34	Rush Sexual Inventory Scale (RSI): Section A			38									
35-37	Rush Sexual Inventory Scale (RSI): Section B (3 pages)			39-41				103-105				155-157	
38	Electrocardiogram (ECG) / Pregnancy Test							85				137	
39	Study Termination Report - Part 1												159
40	MDD Relapse Based on 25-item HAMD Scale												
41	Study Termination Report - Part 2												
42	Adverse Event Form												
43-44	Concomitant Medication Form												
45-47	Serious Adverse Event Form (3 pages)												
48	Adverse Event Follow-up Report												
49	Exposure in Utero												
50	Serious Adverse Event Form - *Page 3 of 3 (Extra Form)*												
51-54	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) (4 pages) - Unscheduled Visit												
55	Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)* - Unscheduled Visit												

AS NEEDED

PROTOCOL M/2020/0034

PART 1: SCHEDULE OF ACTIVITIES

(Check boxes as forms/activities are completed)

Study Activities \ Study Period	Screen	(Week 0)	End of Week 1	2	3	4	5	6	7	8	End of Part 1
Informed Consent	☐										
Eligibility Checklist	☐										
Medical History	☐										
Physical Examination	☐										
Demographic	☐										
Vital Signs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Pregnancy Test	☐					☐				☐	
Electrocardiogram (ECG)	☐					☐				☐	
Social / Occupational Status	☐										
Psychiatric History	☐										
Diagnosis of Depression	☐										
Expectation of Subject	☐										
DSM-IV 5-Axis Clinical Diagnosis	☐									☐	
MGH: Antidepressant Treatment Response Questionnaire	☐										
History of Other Psychoactive Drugs	☐										
Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Study Medication		☐	☐	☐	☐	☐	☐	☐	☐	☐	
Montgomery-Asberg Depression Rating Scale (MADRS)		☐	☐	☐		☐		☐		☐	
Clinical Global Impressions (CGI)		☐	☐	☐		☐		☐		☐	
Patient Global Impressions (PGI)		☐	☐	☐		☐		☐		☐	
SF-36 Health Survey		☐	☐	☐		☐		☐		☐	
Kellner Symptoms Questionnaire (KSQ)		☐	☐	☐		☐		☐		☐	
Social Adaptation Self-evaluation Scale (SASS)		☐	☐	☐		☐		☐		☐	
Rush Sexual Inventory Scale (RSI): Section A		☐									
Rush Sexual Inventory Scale (RSI): Section B		☐				☐				☐	
Study Termination Report - Part 1											☐
Adverse Event Form	**AS NEEDED**										
Concomitant Medication Form											
Serious Adverse Event Form											
Adverse Event Follow-up Report											
Exposure in Utero											
Serious Adverse Event Form - *Page 3 of 3 (Extra Form)*											
Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - Unscheduled Visit											
Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)* - Unscheduled Visit											

PROTOCOL M/2020/0034

SCREEN

If patient signs Informed Consent document, then please do the following:

- Confirm DSM-IV MDD *(by SCID)* and document in patient's chart *(source document)*.
- Complete the following CRFs:

Page #	Form
1-3	Eligibility Checklist
4	Medical History
5	Physical Examination
6	Demographics / Vital Signs / Pregnancy Test / ECG ***NOTE: Mail duplicate original ECG to Premier***
7	Social / Occupational Status
8	Psychiatric History
9	Diagnosis of Depression / Expectation of Subject
10	DSM-IV 5-Axis Clinical Diagnosis
11-12	MGH: Antidepressant Treatment Response Questionnaire
13-14	History of Other Psychoactive Drugs
15-18	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
19	Addendum Hamilton Psychiatric Rating Scale for Depression

- Draw screening laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*

If patient meets eligibility criteria, schedule patient for Day 1 visit within 2 week visit window.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SCREEN

All **Screen** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	1	Eligibility Checklist - *Page 1 of 3*
☐	2	Eligibility Checklist - *Page 2 of 3*
☐	3	Eligibility Checklist - *Page 3 of 3*
☐	4	Medical History
☐	5	Physical Examination
☐	6	Demographics / Vital Signs / Pregnancy Test / ECG
☐	7	Social / Occupational Status
☐	8	Psychiatric History
☐	9	Diagnosis of Depression / Expectation of Subject
☐	10	DSM-IV 5-Axis Clinical Diagnosis
☐	11	MGH: Antidepressant Treatment Response Questionnaire - *Page 1 of 2*
☐	12	MGH: Antidepressant Treatment Response Questionnaire - *Page 2 of 2*
☐	13	History of Other Psychoactive Drugs - *Page 1 of 2*
☐	14	History of Other Psychoactive Drugs - *Page 1 of 2*
☐	15	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	16	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	17	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	18	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	19	Addendum Hamilton Psychiatric Rating Scale for Depression

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ELIGIBILITY CHECKLIST - *Page 1 of 3* SCREEN

DataFax #147 Plate #001 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

INCLUSION CRITERIA: ALL responses must be 'YES' for this subject to enter the study.

	YES	NO
1. Is this patient of either sex, of any race, and aged 18 through 65 years?	☐	☐
2a. Is this patient an outpatient with major depressive disorder (MDD) currently diagnosed with the use of the Structured Clinical Interview for DSM-IV Axis I Disorder (SCID)?	☐	☐
SCID Version used: _____		
b. Is this an outpatient who was diagnosed with a complete Structured Clinical Interview for DSM-IV Axis I Disorder (SCID) prior to fluoxetine treatment and now mood disorders, mood episodes and psychotic screen modules have been repeated to confirm major depressive disorder (MDD) diagnosis within 1 week of screening?	☐	☐
3. Did the patient receive at least 6-12 weeks of daily fluoxetine?	☐	☐
If Yes, list start date ☐☐☐☐☐☐☐☐ *y y y y m m d d*		
and stop date ☐☐☐☐☐☐☐☐ *y y y y m m d d*		
Is the patient currently receiving fluoxetine?	☐	☐
4. Was the fluoxetine dose for the final 3 weeks at least 40 mg/day?	☐	☐
If Yes, what was the actual dose for the final 3 weeks? ☐☐ *mg/day*		
5. Was the CGI-I 3-7 *(minimally improved-very much worse)* for each of the last two weeks of fluoxetine treatment?	☐	☐
6. Did the patient continue to meet the DSM-IV criteria for MDD without Psychotic Features for the last two weeks?	☐	☐
7. Was the patient evaluated using the 25-item HAMD at Screen and had a HAMD score of > 8 prior to Reboxetine dosing?	☐	☐
8. Has the patient provided written informed consent?	☐	☐

ELIGIBILITY CHECKLIST - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #002 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

EXCLUSION CRITERIA: **All responses must be 'NO' or "N/A" for this subject to enter the study.**

	YES	NO	N/A
1. Does patient have a diagnosis of Major Depressive Episode with psychotic features?.....	☐	☐	
2. Does patient have a diagnosis of Cyclothymia disorder?.....	☐	☐	
3. Does patient have a diagnosis of Bipolar I or Bipolar II disorder?.....	☐	☐	
4. Does this patient meet the criteria for DSM-IV diagnosis of Substance Related Disorders within the past 6 months?.....	☐	☐	
5. Does the patient meet criteria for DSM-IV diagnosis of Schizophrenia, or Other Psychotic Disorders?.....	☐	☐	
6. Does this patient have a history of major depressive disorders associated with endocrine disorders: hypo-and hyper-thyroidism tested by TSH and T4; adrenal insufficiency, or Cushing's syndrome?.....	☐	☐	
7. IF A CHILD-BEARING AGE FEMALE, does this patient have a positive pregnancy test or is she breastfeeding currently?.....	☐	☐	☐
8. IF A CHILD-BEARING AGE FEMALE, does this patient refuse to use effective contraceptives during the study period?.....	☐	☐	☐
9. Has the patient participated in any clinical study with an investigational compound in the 4 weeks preceding this study?.....	☐	☐	
10. Does this patient have a history or presence of gastrointestinal, liver, or kidney disease, or other conditions known to interfere with the absorption, distribution, metabolism and excretion of drugs?.....	☐	☐	
11. Does this patient have a history or seizures or brain injury or current evidence of clinically important hematopoietic, respiratory, cardiovascular, urinary retention, or glaucoma disease?.....	☐	☐	

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ELIGIBILITY CHECKLIST - *Page 3 of 3* SCREEN

DataFax #147 Plate #003 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

Exclusion Criteria - Continued

		YES	NO
12.	Has the patient had any important clinical illness in the last 4 weeks which might interfere with the conduct of the trial?.....	☐	☐
13.	Does the patient have any clinically relevant abnormal findings in the physical examination, laboratory tests and ECG at admission?.....	☐	☐
14.	Has the patient had electroconvulsive therapy (ECT) in the previous 6 months?.....	☐	☐
15.	Is there a high risk of suicide as assessed by investigator's judgement or a score ≥ 3 on the HAMD suicide question; or has the patient attempted suicide during this present episode?.....	☐	☐

ANY QUESTIONS REGARDING THIS SUBJECT'S ELIGIBILITY SHOULD BE REFERRED TO THE PRINCIPAL MONITOR.

I verify that this subject: (1) meets all protocol requirements for entry into this study, AND
(2) has freely given his/her informed consent to participate in this study.

COMMENTS:

Investigator's Signature: _____ Date ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MEDICAL HISTORY SCREEN

DataFax #147 Plate #004 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

INSTRUCTIONS: Check appropriate box to indicate medical history of disorders in the areas listed below.

Include any surgeries or hospitalizations under appropriate category. Describe or comment if "*History*" box is checked.

DO NOT INCLUDE PSYCHIATRIC HISTORY

MEDICAL HISTORY

MEDICAL HISTORY		
	HEENT / MOUTH ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	CARDIOVASCULAR ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	PULMONARY ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	GASTROINTESTINAL ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	RENAL / URINARY TRACT ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	MUSCULOSKELETAL ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	NEUROLOGIC *(including convulsive disorders)* ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	DERMATOLOGIC ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	METABOLIC / ENDOCRINE ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	HEMATOLOGIC ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	ALLERGIC ☐ *None* ☐ *History*	DESCRIBE / COMMENT
	OTHER *(Specify)* _____	DESCRIBE / COMMENT

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PHYSICAL EXAMINATION SCREEN

DataFax #147 Plate #005 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (Site No.) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

INSTRUCTIONS: Check appropriate box to indicate current physical findings. Describe any abnormalities, indicating left or right where applicable. If evaluation of the category is not performed, write "Not Done".

PHYSICAL FINDINGS

HEAD AND NECK ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
EENT / MOUTH ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
CHEST / LUNGS ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
HEART ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
BREASTS ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
BACK / SPINE ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
ABDOMEN ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
EXTREMITIES ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
SKIN ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
LYMPH NODES ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
NERVOUS SYSTEM ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
MENTATION ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
ENDOCRINE ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
OTHER ABNORMAL PHYSICAL FINDINGS? ☐ No ☐ Yes	IF YES, BRIEFLY DESCRIBE

COMMENTS:

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

DEMOGRAPHICS / VITAL SIGNS / PREGNANCY TEST / ECG SCREEN

DataFax #147 Plate #006 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (Site No.) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

DEMOGRAPHICS

Sex: ☐ *Male* ☐ *Female* Date of Birth: ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Race: ☐ *Caucasian* ☐ *Black* ☐ *Asian* ☐ *Hispanic* ☐ *American Indian* ☐ *Other (specify)* _____

VITAL SIGNS

Weight *(without shoes)*: ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ (*Systolic*) / ☐☐☐ (*Diastolic*) *mmHg*

Height *(without shoes)*: ☐☐ *in* Temperature: ☐☐☐.☐ °*F*

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

PREGNANCY TEST *(Serum)*

NOT DONE, Reason: ☐ *Male* ☐ *Surgically sterile* ☐ *Postmenopausal (>2 years)*

DONE, Result: ☐ *Negative* ☐ *Positive* ☐ *Inconclusive*

Note: If test is positive or inconclusive, subject is not eligible for this study.

ELECTROCARDIOGRAM *(ECG)*

Date ECG Performed ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

☐ *Normal* ☐ *Abnormal*

Comments, if any: _____

Note: Please mail a duplicate original Electrocardiogram (ECG) to PREMIER.

Initials or Signature: _____

DataFax #147 Plate #007 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

MARITAL STATUS
(check one box)

- ☐ 1 *Never married / Single*
- ☐ 2 *Currently married*
- ☐ 3 *Separated*
- ☐ 4 *Widowed*
- ☐ 5 *Divorced*

HIGHEST EDUCATIONAL LEVEL
(check highest level attained)

- ☐ 1 *Middle school or less*
- ☐ 3 *High school diploma*
- ☐ 5 *Technical school certificate*
- ☐ 7 *College degree*
- ☐ 9 *Graduate school degree*

OCCUPATION GROUP
(check one box)

- ☐ 1 *Managerial and professional specialty occupations*
- ☐ 2 *Technical, sales, and administrative support occupations*
- ☐ 3 *Service Occupations*
- ☐ 4 *Precision production, craft, and repair occupations*
- ☐ 5 *Operators, fabricators, and laborers*
- ☐ 6 *Farming, forestry, and fishing occupations*
- ☐ 7 *Never worked*

LIVING SITUATION In the 3 years preceding the present episode, the subject's residence has primarily been:
(check one box)

- ☐ 1 *With Spouse*
- ☐ 2 *With family (first degree relatives only)*
- ☐ 3 *Alone*
- ☐ 4 *Non-family*
- ☐ 5 *Treatment facility*
- ☐ 6 *With significant other (unmarried)*

CURRENT EMPLOYMENT STATUS
(check one box)

- ☐ 1 *Full-time*
- ☐ 2 *Part-time*
- ☐ 3 *Not employed (by choice)*
- ☐ 4 *Not employed (other)*
- ☐ 99 *Unknown*

Initials or Signature: _____

DataFax #147 Plate #008 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (Site No.) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

TREATMENT STATUS

Immediately prior to screening for this study, the subject was: *(check one box)*

- ☐ 1 *In no hospital treatment*
- ☐ 2 *An outpatient only*
- ☐ 3 *In partial hospitalization (day treatment)*
- ☐ 4 *An inpatient*

HOSPITALIZATION FOR THIS CONDITION

Was subject ever hospitalized? ☐ *No* ☐ *Yes*

If *Yes*, continue: → Number of hospitalizations ☐☐

Date of first hospitalization ☐☐ / ☐☐☐☐ (month / year)

HISTORY OF PSYCHOTROPIC MEDICATION USE

Has subject ever been treated with psychotropic medication(s) other than anti-depressants?

☐ *No* ☐ *Yes* → If *Yes*, with what type of medications?

- ☐ 1 *Benzodiazepines*
- ☐ 2 *Anxiolytics other than benzodiazepines*
- ☐ 3 *Anti-psychotics*
- ☐ 4 *Mood stabilizer including Lithium*

Do any of the subject's first degree relatives have a history of:
(Please check all that apply)

- ☐ 1 *No known family history*
- ☐ 2 *Major Depression* _____ (Relationship)
- ☐ 3 *Schizophrenia* _____ (Relationship)
- ☐ 4 *Schizoaffective Disorder* _____ (Relationship)
- ☐ 5 *Bipolar disorder* _____ (Relationship)
- ☐ 6 *Other (specify)* _____ (Relationship)

Initials or Signature: _____

DataFax #147 Plate #009 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

HISTORY OF DEPRESSION

Age at onset of first major depressive episode: ☐☐ *years*

Number of previous episodes: ☐☐

Approximate duration of last episode in: ☐☐ *weeks*, ☐☐ *months*, ☐☐ *years*

If recurrent, approximate interepisode duration *(from last episode):* ☐☐ *weeks*, ☐☐ *months*, ☐☐ *years*

PRESENT EPISODE

Approximate duration of current episode at the time of admission to the study in: ☐☐ *days*, ☐☐ *weeks*, ☐☐ *months*, ☐☐ *years*

The present episode is BEST characterized as:

- ☐ 1 *Exacerbation of chronic condition*
- ☐ 2 *Recurrence of similar previous conditions*
- ☐ 3 *Significantly different from any previous conditions*
- ☐ 4 *First occurrence, no previous psychiatric diagnosis*

Precipitating external stress was:

- ☐ 1 *Absent*
- ☐ 2 *Probably present*
- ☐ 3 *Definitely present*

EXPECTATION OF SUBJECT

Do you expect Reboxetine to be:
- ☐ 1 *Not effective*
- ☐ 2 *Somewhat effective*
- ☐ 3 *Very effective*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

DSM-IV 5-AXIS CLINICAL DIAGNOSIS SCREEN

DataFax #147 Plate #010 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

DSM-IV 5-AXIS CLINICAL DIAGNOSIS

AXIS	CODE	NAME
Axis I (DSM-IV)	☐☐☐.☐☐	
	☐☐☐.☐☐	
	☐☐☐.☐☐	
	☐☐☐.☐☐	
Axis II (DSM-IV)	☐☐☐.☐☐	
	☐☐☐.☐☐	
	☐☐☐.☐☐	
Axis III (ICD-9-CM)	☐☐☐.☐☐	
	☐☐☐.☐☐	

Axis IV ***Please check all that applies:***

- ☐ 1 *Problems with primary support group*
- ☐ 2 *Problems related to the social environment*
- ☐ 3 *Educational problems*
- ☐ 4 *Occupational problems*
- ☐ 5 *Housing problems*
- ☐ 6 *Economic problems*
- ☐ 7 *Problems with access to health care services*
- ☐ 8 *Problems related to interaction with legal system/crime*
- ☐ 9 *Other psychosocial and environmental problems*

Specify: _____

COMMENTS: _____

Axis V Current Score: ☐☐☐

Extreme Mood reactivity present..... ☐ *No* ☐ *Yes*

Rejection sensitivity present..... ☐ *No* ☐ *Yes*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MGH: ANTIDEPRESSANT TREATMENT RESPONSE QUESTIONNAIRE - ***Page 1 of 2*** SCREEN

DataFax #147 Plate #011 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MGH

INSTRUCTIONS: Please indicate the correct answer to the following questions:

1. Have you received any treatment with medications since the beginning of THIS episode or period of depression?

   ☐ *Yes ** ☐ *No*

   If Yes, please answer the questions on the next page.

2. Of the medications that you have checked on the next page, which one do you feel helped you the most with your depression. Please write medication number: ☐☐

3. If a rating of 100 is "completely improved" and 0 is "not improved at all", how close to 100 did you get on this medication? Please check the answer that best applies to you.

   ☐ 1 *Less than 25% improved*
   ☐ 2 *Between 25% and 49% improved*
   ☐ 3 *Between 50% and 75% improved*
   ☐ 4 *More than 75% improved*

4. For Fluoxetine, please check the answer that best applies to you.

   ☐ 1 *Less than 25% improved*
   ☐ 2 *Between 25% and 49% improved*
   ☐ 3 *Between 50% and 75% improved*
   ☐ 4 *More than 75% improved*

MGH: ANTIDEPRESSANT TREATMENT RESPONSE QUESTIONNAIRE- *Page 1 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MGH: ANTIDEPRESSANT TREATMENT RESPONSE QUESTIONNAIRE - ***Page 2 of 2***

SCREEN

DataFax #147 Plate #012 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MGH - Continued

INSTRUCTIONS: Please check the names of any medications that you have taken for at least 6 weeks since the beginning of THIS episode or period of depression. Please also check if your daily dosage of the medication was equal to or greater than the minimum dose listed below and whether it was discontinued because of side-effects.:

DRUG CLASS

No.	Brand Name(s)	Generic Name	Check if taken for at least 6 weeks	Minimum Dose	Check if dose was equal to or greater than	Was this discontinued because of side-effects	
						Yes	**No**
Tricyclic Antidepressants							
1.	Adapin	doxepin	☐	150 mg per day	☐	☐	☐
2.	Anafranil	clomipramine	☐	150 mg per day	☐	☐	☐
3.	Asendin	amoxapine	☐	150 mg per day	☐	☐	☐
4.	Erdep or Elavil	amitriptyline	☐	150 mg per day	☐	☐	☐
5.	Ludiomil	maprotiline	☐	150 mg per day	☐	☐	☐
6.	Norpramin	desipramine	☐	150 mg per day	☐	☐	☐
7.	Pamelor	nortriptyline	☐	75 mg per day	☐	☐	☐
8.	Sinequan	doxepin	☐	150 mg per day	☐	☐	☐
9.	Surmontil	trimipramine	☐	150 mg per day	☐	☐	☐
10.	Tofranil	imipramine	☐	150 mg per day	☐	☐	☐
11.	Vivactil	protriptyline	☐	40 mg per day	☐	☐	☐
Monoamine Oxidase Inhibitors (MAOIs)							
12.	Marplan	isocarboxazid	☐	45 mg per day	☐	☐	☐
13.	Nardil	phanelzine	☐	45 mg per day	☐	☐	☐
14.	Parnate	tranylcypromine	☐	30 mg per day	☐	☐	☐
Selective Serotonin Reuptake Inhibitors (SSRIs)							
15.	Luvox	fluvoxamine	☐	50 mg per day	☐	☐	☐
16.	Paxil	paroxetine	☐	20 mg per day	☐	☐	☐
17.	Prozac	fluoxetine	☐	20 mg per day	☐	☐	☐
18.	Zoloft	sertraline	☐	50 mg per day	☐	☐	☐
19.	Celexa	citalopram	☐	20 mg per day	☐	☐	☐
Others							
20.	Desyrel	trazodone	☐	300 mg per day	☐	☐	☐
21.	Serzone	nefazodone	☐	300 mg per day	☐	☐	☐
22.	Wellbutrin	bupropion	☐	300 mg per day	☐	☐	☐
23.	Effexor	venlafaxine	☐	125 mg per day	☐	☐	☐
24.	Remeron	mirtazapine	☐	15 mg per day	☐	☐	☐
25.	Other	_____	☐	_____	☐	☐	☐

Reviewer's Initials: _____

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MGH: ANTIDEPRESSANT TREATMENT RESPONSE QUESTIONNAIRE- *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HISTORY OF OTHER PSYCHOACTIVE DRUGS - *Page 1 of 2* SCREEN

DataFax #147 Plate #013 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

HISTORY OF OTHER PSYCHOACTIVE DRUGS - *Page 1 of 2*

Has subject taken any other psychoactive *(including alcohol and illicit)* drugs DURING THE MONTH PRIOR TO SCREEN? *If No, check the NO box to the right and sign at the bottom of the page. If Yes, record the medication on this form.* ☐ ***No***

	Medication Trade or Generic Name					**To Be Continued?**
001	_____	*Dose Amount*	*Units*	*Frequency*	*Route*	*Reason for Use of Medication (Major Diagnosis)*	**Date Started** *y y y y m m d d* ☐☐☐☐ ☐☐ ☐☐ **Date Stopped** ☐☐☐☐ ☐☐ ☐☐	☐ *No* ☐ *Yes*
002	_____	*Dose Amount*	*Units*	*Frequency*	*Route*	*Reason for Use of Medication (Major Diagnosis)*	**Date Started** *y y y y m m d d* ☐☐☐☐ ☐☐ ☐☐ **Date Stopped** ☐☐☐☐ ☐☐ ☐☐	☐ *No* ☐ *Yes*
003	_____	*Dose Amount*	*Units*	*Frequency*	*Route*	*Reason for Use of Medication (Major Diagnosis)*	**Date Started** *y y y y m m d d* ☐☐☐☐ ☐☐ ☐☐ **Date Stopped** ☐☐☐☐ ☐☐ ☐☐	☐ *No* ☐ *Yes*
004	_____	*Dose Amount*	*Units*	*Frequency*	*Route*	*Reason for Use of Medication (Major Diagnosis)*	**Date Started** *y y y y m m d d* ☐☐☐☐ ☐☐ ☐☐ **Date Stopped** ☐☐☐☐ ☐☐ ☐☐	☐ *No* ☐ *Yes*

Protocol M/2020/0034 (FINAL 19APR99)

COMMENTS *(Record the line number for each comment):*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HISTORY OF OTHER PSYCHOACTIVE DRUGS - *Page 2 of 2* SCREEN

DataFax #147 Plate #014 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

HISTORY OF OTHER PSYCHOACTIVE DRUGS - *Page 2 of 2*

History of other Psychoactive drugs - Continued

Medication Trade or Generic Name	Date Started (*y y y y m m d d*)	Date Stopped	To Be Continued?	Dose Amount	Units	Frequency	Route	Reason for Use of Medication (Major Diagnosis)
☐☐☐ _____			☐ No ☐ Yes					
☐☐☐ _____			☐ No ☐ Yes					
☐☐☐ _____			☐ No ☐ Yes					
☐☐☐ _____			☐ No ☐ Yes					

COMMENTS *(Record the line number for each comment):*

Initials or Signature: _____

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

How have you been feeling recently?

Have you felt low in spirit, gloomy, or depressed?

What percentage of time over the past week have you felt this way?

---

2. Distinct quality of mood

Can you describe your feelings a bit more?

Is this feeling different from the feeling you might get or have had after reading an emotional story *(or seeing an emotional movie)*?

Is it different from the feeling you might get or have had after someone close to you has died?

---

3. Lack of reactivity

Do you find it difficult to turn your attention away from your mood *(depression)*?

Have there been times over the past week when your mood has changed?

Have there been times when you felt better?

Can you think of anything that has happened over the past week *(other than taking medication)* that has made you feel better?

How long did this feeling last?

---

4. Diurnal variation

Is your depression *regularly* worse at any particular time of day?

In the morning?

In the afternoon?

In the evening?

---

5. Worthlessness

What is your opinion of yourself compared to other people?

Do you think of yourself as better, not as good, or about the same as most other people?

Do you feel inferior, or even worthless compared to others?

Are there things about yourself that you like?

---

6. Guilt

Are you critical of yourself for your weaknesses or mistakes?

Do you blame yourself for things that go wrong around you even if others seem to think that you didn't have anything to do with them?

Do you think your present illness is some type of punishment for something?

Do you hear voices threatening or accusing you?

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4*** SCREEN

DataFax #147 Plate #015 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

7. Helplessness

Do you feel you're in control of your life?

Are there things in your life that you would like to change but are unable to?

Have there been times lately when it seems that no matter what *you* do, you just can't change things for the better?

---

8. Hopelessness

How do you see the future?

Do you feel hopeless, that things won't get better?

Are these thoughts fleeting, do they seem to occur for a while and then go away, or are they continuous *(can't get them out of your mind?)*

When you talk about these feelings with others, does it help? Can you be reassured?

---

9. Suicide

Do you feel that life is worth living?

Do you wish you were dead?

Do you have thoughts of committing suicide?

Have you tried to kill yourself?

Insomnia

Do you have trouble sleeping?

10. Early

Do you have trouble falling asleep?

How long does it take you to fall asleep?

How often?

11. Middle

Once you get to sleep do you wake up during the night?

What do you do when you wake up?

Can you get back to sleep?

12. Late

Do you wake up earlier than your usual time *(before onset of depression)* in the morning?

Can you go back to sleep?

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 2 of 4*** SCREEN

DataFax #147 Plate #016 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Page 16

25-ITEM HAMD - *Page 2 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

13. Loss of appetite

How is your appetite compared to the way it usually is?

Do you have trouble with constipation or other problems with your stomach or bowels?

14. Loss of weight

Over the *past month*, when not dieting, have you lost any weight?

15. Weight gain

Over the *past month* have you gained weight? How much?

---

16. Loss of energy

Have you had less energy than usual, or have you been getting tired more easily?

How has this affected your work or other activities?

Have your back, head, or limbs felt heavy or ached?

17. Loss of interest

Do you find that you have lost interest in or get less pleasure from the things that you used to enjoy?

Have you wanted to stay away from other people?

Have you stopped seeking out others for company *(e.g., stopped calling people)*?

Do you actively avoid others when they seek you out *(e.g., won't come to the phone or go out with others when invited)*?

Have you lost interest in work, hobbies, or recreational activities?

Have you let your appearance go?

18. Work and activities

Do you find that you have trouble doing things you really need to do *(e.g., job, housework, studies)*?

How has this decreased interest in things and/or people affected your life?

19. Loss of libido

Over the *past month* has there been any change in your interest in sex?

Does this represent a change from the way you usually feel about sex?

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

Have there been times lately that you felt very anxious or frightened?

Are these feelings fleeting, do they occur for a while and then go, or are they continuous?

What percentage of the time over the past week would you say that you have felt this way?

What kinds of situations did you feel anxious in?

Have you been in any situation where you were so anxious that you simply had to get out, run, or do something else about it?

DataFax #147 Plate #017 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

---

21. Somatic anxiety - *(**Note:** Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

When you felt anxious, what was it like?

Did you notice your heart beating faster?

(Ask about other somatic symptoms noted above)

Have these bodily changes hindered your performance in any way?

---

22. Hypochondriasis

How is your physical health?

Do you tend to worry about your health?

Are you so concerned with your health that you find it hard to think about other things?

*(**Important:** Interviewer is evaluating the extent to which the patient focuses on physical health to the exclusion of other symptoms)*

---

23. Insight ***(patient background should be taken into account)***

Do you think there is anything the matter with you?

What do you think it is?

Could it be that you have emotional problems?

---

24. Retardation ***(direct observation)***

---

25. Agitation ***(direct observation)***

DataFax #147 Plate #018 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)*** SCREEN

DataFax #147 Plate #019 Seq. #000

Subject Number ☐☐ - ☐☐☐☐ (Site No.) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

DAY 1

- Complete the following CRFs:

Page #	Form
20	Vital Signs / AE & Concomitant Medication / Study Medication Record
21-24	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
25	Addendum Hamilton Psychiatric Rating Scale for Depression
26-28	Montgomery - Asberg Depression Rating Scale (MADRS)
29	Clinical Global Impressions (CGI)
30	Patient Global Impressions (PGI)
31-33	SF-36 Health Survey
34-35	Kellner Symptom Questionnaire (KSQ)
36-37	Social Adaptation Self-Evaluation Scale (SASS)
38	Rush Sexual Inventory Scale (RSI): Section A
39-41	Rush Sexual Inventory Scale (RSI): Section B

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 20)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

If patient remains eligible, enroll subject into study by:

- Obtaining the next sequential Part 1 study medication box and assigning the subject number (e.g., 1001) indicated on the box to this patient.
- Dispense Week 1's supply of study medication to the patient. Give Part 1 Dosing Diary, Dosing Diary instructions and dosing instructions.
- Schedule patient for End of Week 1 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

DAY 1

All **Day 1** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	20	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	21	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	22	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	23	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	24	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	25	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	26	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	27	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	28	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	29	Clinical Global Impressions (CGI)
☐	30	Patient Global Impressions (PGI)
☐	31	SF-36 Health Survey - *Page 1 of 3*
☐	32	SF-36 Health Survey - *Page 2 of 3*
☐	33	SF-36 Health Survey - *Page 3 of 3*
☐	34	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	35	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	36	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	37	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	38	Rush Sexual Inventory Scale (RSI): Section A
☐	39	Rush Sexual Inventory Scale (RSI): Section B - *Page 1 of 3*
☐	40	Rush Sexual Inventory Scale (RSI): Section B - *Page 2 of 3*
☐	41	Rush Sexual Inventory Scale (RSI): Section B - *Page 3 of 3*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form

DataFax #147 Plate #020 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes)*: ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

ADVERSE EVENTS AND CONCOMITANT MEDICATION

Does the subject have any adverse events/complaints now?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Is the subject taking any concomitant medication?

☐ *No* ☐ *Yes* If *Yes,* record the medication(s) on the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets dispensed at DAY 1: ☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4*** DAY 1

DataFax #147 Plate #015 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

☐ 0 *Absent*
☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
☐ 4 *Extreme symptoms - complete withdrawal*
☐ *Can't rate*

2. Distinct quality of mood

☐ 0 *No distinct qualities*
☐ 1 *Mild or moderate (slightly different)*
☐ 2 *Severe (definitely different)*
☐ *Can't rate*

3. Lack of reactivity

☐ 0 *Reactive mood (mood varies according to situation)*
☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
☐ *Can't rate*

4. Diurnal variation

☐ 0 *No variation in mood*
☐ 1 *Mild variation between a.m. and p.m.*
☐ 2 *Definite variation between a.m. and p.m.*
☐ *Can't rate*

5. Worthlessness

☐ 0 *Not present*
☐ 1 *Mild feelings of low self-esteem evident only from questioning*
☐ 2 *Feelings of worthlessness*
☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
☐ *Can't rate*

6. Guilt

☐ 0 *Absent*
☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
☐ 4 *Delusional guilt, with hallucinations*
☐ *Can't rate*

DataFax #147 Plate #016 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4*** DAY 1

DataFax #147 Plate #018 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Page 24

25-ITEM HAMD - *Page 4 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)*** DAY 1

DataFax #147 Plate #019 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

DAY 1

DataFax #147 Plate #022 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 3 of 3*** DAY 1

DataFax #147 Plate #024 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

☐ 0 *Normal interest in the surroundings and in other people.*
☐ 1
☐ 2 *Reduced ability to enjoy usual interests.*
☐ 3
☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
☐ 5
☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

☐ 0 *No pessimistic thought.*
☐ 1
☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
☐ 3
☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
☐ 5
☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

☐ 0 *Enjoys life or takes it as it comes.*
☐ 1
☐ 2 *Weary of life. Only fleeting suicidal thought.*
☐ 3
☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
☐ 5
☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

DataFax #147 Plate #025 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Principal Investigator _____ ☐☐☐☐☐
Country US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

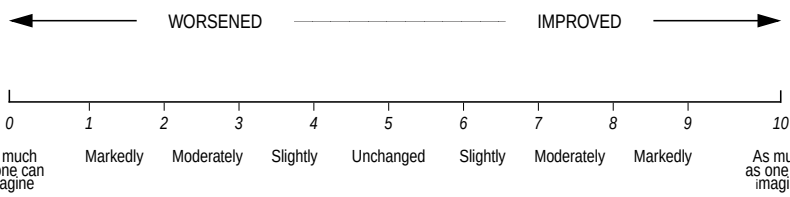
Initials or Signature: _____

DataFax #147 Plate #026 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Principal Investigator _____ ☐☐☐☐☐
Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE START OF FLUOXETINE TREATMENT MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3* DAY 1

DataFax #147 Plate #027 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #028 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - *Page 1 of 2* DAY 1

DataFax #147 Plate #030 Seq. #001

Subject Number ___ ___ - ___ ___ ___ ___ (*Site No.*) **Subject's Initials** ___ ___ ___ (*F M L*) **Date of Evaluation** ___ ___ ___ ___ ___ ___ ___ ___ (*y y y y m m d d*)

Principal Investigator _____ ___ ___ ___ ___ ___ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

KSQ - *Page 1 of 2*

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

Protocol M/2020/0034 (FINAL 19APR99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - *Page 2 of 2* DAY 1

DataFax #147 Plate #031 Seq. #001

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Principal Investigator _____ ___ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
	Yes	**No**
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

DAY 1

DataFax #147 Plate #032 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 19APR99)

Page 36

DataFax #147 Plate #033 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

RUSH SEXUAL INVENTORY SCALE (RSI): SECTION A DAY 1

DataFax #147 Plate #034 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI (Note: Questions #1-6 on this page only applies to DAY 1 visit)

1. Have you ever experienced sexual dysfunction while taking any medication?

   ☐ *No* ☐ *Yes, explain:* _____

2. Do you and/or your sexual partner(s) presently use birth control?

   ☐ *No* ☐ *Not Applicable (no partner)*

   ☐ *Yes, check all that apply:*

   - ☐ 1 *condom*
   - ☐ 2 *diaphragm*
   - ☐ 3 *foam*
   - ☐ 4 *rhythm method*
   - ☐ 5 *birth control pills*
   - ☐ 6 *intrauterine device (IUD)*
   - ☐ 7 *sterilization (vasectomy, tubal ligation, hysterectomy)*
   - ☐ 8 *withdrawal of penis from vagina prior to ejaculation*
   - ☐ 99 *other, explain:* _____

3. Have you ever had any surgical or medical procedure performed on your reproductive organs *(for example, hysterectomy, prostate surgery, penile implant, hymenectomy, etc.)*?

   ☐ *No* ☐ *Yes, explain:* _____

4. Have you ever had a non-routine investigation of your reproductive organs?

   ☐ *No* ☐ *Yes, explain:* _____

5. Have you ever been evaluated for a sexual dysfunction?

   ☐ *No* ☐ *Yes, explain:* _____

   Have you ever received treatment for a sexual dysfunction?

   ☐ *No* ☐ *Yes, explain:* _____

6. Please list any circumstances in your life that you feel may have affected your sexual experience *(either positively or negatively).* Include dates, when appropriate.

   _____

   _____

RSI: SECTION A

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

RUSH SEXUAL INVENTORY SCALE (RSI):
SECTION B - ***Page 1 of 3***

DAY 1

DataFax #147 Plate #035 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI

1. Rate each item as it applies in the PAST 4 WEEKS. For each item below, place a mark on the line where you would place yourself.

Example:

infrequent — *very frequent*

a. How frequently do you have pleasurable sexual thoughts?

infrequent — *very frequent*

b. Rate your ability to become sexually excited:

unable — *always able*

c. How frequently do you have desires to initiate sexual activity?

infrequent — *very frequent*

d. How often do you initiate sexual activity?

infrequent — *very frequent*

e. Rate your overall degree of sexual satisfaction attained:

low — *high*

2. How many times on average in the PAST 4 WEEKS did you engage in the following sexual activities?

Masturbation *(solitary or by partner)*:	**Intercourse *(anal or vaginal)*:**	**Oral sex:**
☐ *0 Never*	☐ *0 Never*	☐ *0 Never*
☐ *1 Once per week*	☐ *1 Once per week*	☐ *1 Once per week*
☐ *2 2-4 times per week*	☐ *2 2-4 times per week*	☐ *2 2-4 times per week*
☐ *3 5-10 times per week*	☐ *3 5-10 times per week*	☐ *3 5-10 times per week*
☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*

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RSI: SECTION B - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #036 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

RSI: Section B - Continued

MALES ONLY ☐ *N/A (female patient); If N/A is checked, go to question 3b.*

3a. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Spontaneous daytime erections	☐	☐
2. Painful erections	☐	☐
3. Erection when sexually aroused	☐	☐
4. Difficulty getting an erection when sexually stimulated	☐	☐
5. Difficulty maintaining an erection to complete sexual act	☐	☐
6. Waking up from sleep with an erection	☐	☐
7. Requiring more stimuli than usual to achieve an erection	☐	☐
8. Requiring more stimuli than usual to maintain an erection	☐	☐
9. Decreased fullness of erection	☐	☐
10. Increased sensitivity of genitals upon physical stimulation	☐	☐
11. Decreased sensitivity of genitals upon physical stimulation	☐	☐
12. Orgasm	☐	☐
13. Ejaculation	☐	☐
14. Painful orgasm/ejaculation	☐	☐
15. Orgasm without ejaculation	☐	☐
16. Delay in achieving orgasm/ejaculation but eventually doing so	☐	☐
17. Inability to achieve orgasm/ejaculation	☐	☐
18. Orgasm without erection	☐	☐
19. Orgasm occurring during sleep	☐	☐
20. Genital pain during sexual contact	☐	☐
21. Orgasm/ejaculation occurring earlier than desired	☐	☐
22. Experiencing orgasm without sexual provocation *(spontaneously, except in sleep)*	☐	☐
23. Generally decreased intensity of orgasm	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

RUSH SEXUAL INVENTORY SCALE (RSI):
SECTION B - ***Page 3 of 3***

DAY 1

DataFax #147 Plate #037 Seq. #001

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

FEMALES ONLY ☐ *N/A (male patient)*

3b. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Increased sensitivity, other than pain, in breasts upon physical contact	☐	☐
2. Increased sensitivity of genitals, other than pain, upon physical contact	☐	☐
3. Pain in breasts upon physical contact	☐	☐
4. Pain in genitals upon physical contact	☐	☐
5. Decreased sensitivity in breasts upon physical contact	☐	☐
6. Decreased sensitivity in genitals upon physical contact	☐	☐
7. Inadequate swelling or vaginal lubrication during sexual arousal	☐	☐
8. Orgasm	☐	☐
9. Multiple orgasm	☐	☐
10. Difficulty achieving orgasm, but eventually being able to	☐	☐
11. Inability to achieve orgasm	☐	☐
12. Experiencing orgasm without sexual provocation *(spontaneously)*	☐	☐
13. Painful orgasm	☐	☐
14. Decreased intensity or orgasm	☐	☐
15. Involuntary vaginal contractions that prevent vaginal penetration	☐	☐
If Yes check one: ☐ *always* ☐ *intermittently*		
16. Physical pain during sexual activity	☐	☐

What was the first day of your last menstrual period: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) ☐ *Not Applicable*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 1

- Complete the following CRFs:

Page #	Form
42	Vital Signs / AE & Concomitant Medication / Study Medication Record
43-46	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
47	Addendum Hamilton Psychiatric Rating Scale for Depression
48-50	Montgomery - Asberg Depression Rating Scale (MADRS)
51	Clinical Global Impressions (CGI)
52	Patient Global Impressions (PGI)
53-55	SF-36 Health Survey
56-57	Kellner Symptom Questionnaire (KSQ)
58-59	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 42)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 42)*. Review dosing instructions if indicated.

- Dispense Week 2's supply of study medication.

- Schedule patient for End of Week 2 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 1

All **End of Week 1** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	42	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	43	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	44	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	45	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	46	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	47	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	48	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	49	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	50	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	51	Clinical Global Impressions (CGI)
☐	52	Patient Global Impressions (PGI)
☐	53	SF-36 Health Survey - *Page 1 of 3*
☐	54	SF-36 Health Survey - *Page 2 of 3*
☐	55	SF-36 Health Survey - *Page 3 of 3*
☐	56	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	57	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	58	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	59	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 1

DataFax #147 Plate #021 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ (*Systolic*) / ☐☐☐ (*Diastolic*) *mmHg*

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 1

DataFax #147 Plate #015 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Page 43

DataFax #147 Plate #016 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 1

DataFax #147 Plate #017 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #018 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 1

DataFax #147 Plate #019 Seq. #101

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Principal Investigator _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 1

DataFax #147 Plate #022 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 1

DataFax #147 Plate #025 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

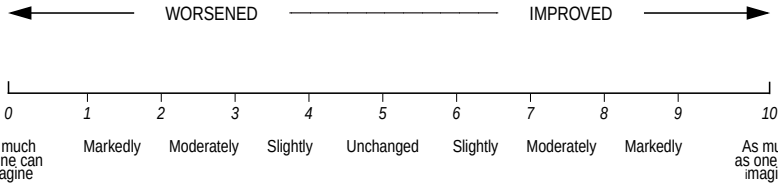
DataFax #147 Plate #026 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 1

DataFax #147 Plate #027 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #028 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Principal Investigator _____ ☐☐☐☐☐
Country US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 1

DataFax #147 Plate #030 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 1

DataFax #147 Plate #031 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 1

DataFax #147 Plate #032 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 19APR99)

Page 58

DataFax #147 Plate #033 Seq. #101

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 2

- Complete the following CRFs:

Page #	Form
60	Vital Signs / AE & Concomitant Medication / Study Medication Record
61-64	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
65	Addendum Hamilton Psychiatric Rating Scale for Depression
66-68	Montgomery - Asberg Depression Rating Scale (MADRS)
69	Clinical Global Impressions (CGI)
70	Patient Global Impressions (PGI)
71-73	SF-36 Health Survey
74-75	Kellner Symptom Questionnaire (KSQ)
76-77	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 60)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 60).* Review dosing instructions if indicated.

- Dispense Week 3's supply of study medication.

- Schedule patient for End of Week 3 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 2

All **End of Week 2** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	60	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	61	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	62	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	63	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	64	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	65	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	66	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	67	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	68	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	69	Clinical Global Impressions (CGI)
☐	70	Patient Global Impressions (PGI)
☐	71	SF-36 Health Survey - *Page 1 of 3*
☐	72	SF-36 Health Survey - *Page 2 of 3*
☐	73	SF-36 Health Survey - *Page 3 of 3*
☐	74	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	75	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	76	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	77	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 2

DataFax #147 Plate #021 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 2

DataFax #147 Plate #015 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Page 61

DataFax #147 Plate #016 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

End of Week 2

DataFax #147 Plate #018 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 2

DataFax #147 Plate #019 Seq. #102

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Principal Investigator _____ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 2

DataFax #147 Plate #022 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 3 of 3***

End of Week 2

DataFax #147 Plate #024 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 2

DataFax #147 Plate #025 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

CLINICAL GLOBAL IMPRESSIONS (CGI)

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PATIENT GLOBAL IMPRESSIONS (PGI)

End of Week 2

DataFax #147 Plate #026 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

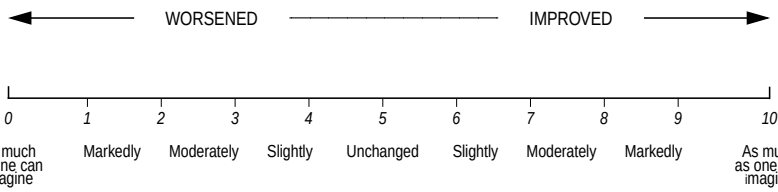
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 2

DataFax #147 Plate #027 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #028 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Principal Investigator _____ ☐☐☐☐☐
Country US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 2

DataFax #147 Plate #030 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 2

DataFax #147 Plate #031 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 2

DataFax #147 Plate #032 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ *3 A lot of enjoyment?* ☐ *2 Some enjoyment?* ☐ *1 Only a little enjoyment?* ☐ *0 No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

5. Is the quality of your spare time:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ *3 Very frequently* ☐ *2 Frequently* ☐ *1 Rarely* ☐ *0 Never*

7. Is the state of relations in your family:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ *3 Many people?* ☐ *2 Some people?* ☐ *1 Only a few people?* ☐ *0 Nobody?*

9. Do you try to form relationships with others:
   ☐ *3 Very actively?* ☐ *2 Actively?* ☐ *1 Moderately actively?* ☐ *0 In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ *3 Very good* ☐ *2 Good* ☐ *1 Fair* ☐ *0 Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 19APR99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 2 of 2*

End of Week 2

DataFax #147 Plate #033 Seq. #102

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 3

- Complete the following CRFs:

Page #	Form
78	Vital Signs / AE & Concomitant Medication / Study Medication Record
79-82	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
83	Addendum Hamilton Psychiatric Rating Scale for Depression

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 78).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 78).* Review dosing instructions if indicated.

- Dispense Week 4's supply of study medication.

- Schedule patient for End of Week 4 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 3

All **End of Week 3** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	**Page #**	**Form**
☐	78	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	79	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	80	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	81	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	82	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	83	Addendum Hamilton Psychiatric Rating Scale for Depression

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 3

DataFax #147 Plate #021 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ (*Systolic*) / ☐☐☐ (*Diastolic*) *mmHg*

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 3

DataFax #147 Plate #015 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #016 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 3

DataFax #147 Plate #017 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #018 Seq. #103

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 3

DataFax #147 Plate #019 Seq. #103

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Principal Investigator _____ ___ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal
- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General
- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms
- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping
- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:
- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 4

- Complete the following CRFs:

Page #	Form
84	Vital Signs / AE & Concomitant Medication / Study Medication Record
85	Electrocardiogram (ECG) *(Note: Mail duplicate original ECG to Premier)*
86-89	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
90	Addendum Hamilton Psychiatric Rating Scale for Depression
91-93	Montgomery - Asberg Depression Rating Scale (MADRS)
94	Clinical Global Impressions (CGI)
95	Patient Global Impressions (PGI)
96-98	SF-36 Health Survey
99-100	Kellner Symptom Questionnaire (KSQ)
101-102	Social Adaptation Self-Evaluation Scale (SASS)
103-105	Rush Sexual Inventory Scale (RSI): Section B

- Draw safety laboratory *(Chemistry panel, CBC, UA)*

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 84)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 84)*. Review dosing instructions if indicated.

- Dispense Week 5's supply of study medication.

- Schedule patient for End of Week 5 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 4

All **End of Week 4** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	84	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	85	Electrocardiogram (ECG)
☐	86	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	87	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	88	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	89	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	90	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	91	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	92	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	93	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	94	Clinical Global Impressions (CGI)
☐	95	Patient Global Impressions (PGI)
☐	96	SF-36 Health Survey - *Page 1 of 3*
☐	97	SF-36 Health Survey - *Page 2 of 3*
☐	98	SF-36 Health Survey - *Page 3 of 3*
☐	99	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	100	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	101	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	102	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	103	Rush Sexual Inventory Scale (RSI): Section B - *Page 1 of 3*
☐	104	Rush Sexual Inventory Scale (RSI): Section B - *Page 2 of 3*
☐	105	Rush Sexual Inventory Scale (RSI): Section B - *Page 3 of 3*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 4

DataFax #147 Plate #021 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Initials or Signature: _____

DataFax #147 Plate #038 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

ELECTROCARDIOGRAM *(ECG)*

Date ECG Performed ☐☐☐☐☐☐☐☐ *y y y y m m d d* Time ☐☐:☐☐ *hours* *(00:01 - 24:00)*

Date of last dose of study medication ☐☐☐☐☐☐☐☐ *y y y y m m d d* Time ☐☐:☐☐ *hours* *(00:01 - 24:00)*

Are there any clinically significant changes noted from Screen ECG? ☐ *No* ☐ *Yes*

Note: Please mail a duplicate original Electrocardiogram (ECG) to PREMIER.

ECG

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 4

DataFax #147 Plate #015 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

☐ 0 *Absent*
☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
☐ 4 *Extreme symptoms - complete withdrawal*
☐ *Can't rate*

2. Distinct quality of mood

☐ 0 *No distinct qualities*
☐ 1 *Mild or moderate (slightly different)*
☐ 2 *Severe (definitely different)*
☐ *Can't rate*

3. Lack of reactivity

☐ 0 *Reactive mood (mood varies according to situation)*
☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
☐ *Can't rate*

4. Diurnal variation

☐ 0 *No variation in mood*
☐ 1 *Mild variation between a.m. and p.m.*
☐ 2 *Definite variation between a.m. and p.m.*
☐ *Can't rate*

5. Worthlessness

☐ 0 *Not present*
☐ 1 *Mild feelings of low self-esteem evident only from questioning*
☐ 2 *Feelings of worthlessness*
☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
☐ *Can't rate*

6. Guilt

☐ 0 *Absent*
☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
☐ 4 *Delusional guilt, with hallucinations*
☐ *Can't rate*

DataFax #147 Plate #016 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

DataFax #147 Plate #018 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 4

DataFax #147 Plate #019 Seq. #104

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Principal Investigator _____ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 4

DataFax #147 Plate #022 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 4

DataFax #147 Plate #025 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

CLINICAL GLOBAL IMPRESSIONS (CGI)

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

PATIENT GLOBAL IMPRESSIONS (PGI)

DataFax #147 Plate #026 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

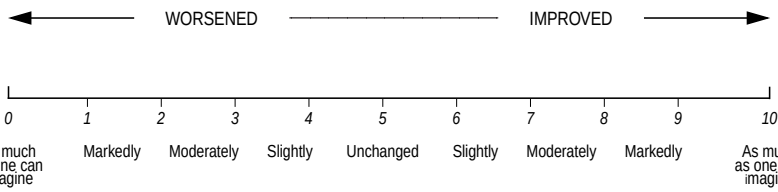
Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 4

DataFax #147 Plate #027 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

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DataFax #147 Plate #028 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 4

DataFax #147 Plate #030 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Page 99

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 4

DataFax #147 Plate #031 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐

	True	False
61. Not interested in things	☐	☐

	Yes	No
62. Highly strung	☐	☐

	True	False
63. Cannot relax	☐	☐

	Yes	No
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐

	True	False
78. No unpleasant feelings in head or body	☐	☐

	Yes	No
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

Page 100

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 4

DataFax #147 Plate #032 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 19APR99)

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DataFax #147 Plate #033 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

DataFax #147 Plate #035 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI

1. Rate each item as it applies in the PAST 4 WEEKS. For each item below, place a mark on the line where you would place yourself.

Example:

infrequent — *very frequent*

a. How frequently do you have pleasurable sexual thoughts?

infrequent — *very frequent*

b. Rate your ability to become sexually excited:

unable — *always able*

c. How frequently do you have desires to initiate sexual activity?

infrequent — *very frequent*

d. How often do you initiate sexual activity?

infrequent — *very frequent*

e. Rate your overall degree of sexual satisfaction attained:

low — *high*

2. How many times on average in the PAST 4 WEEKS did you engage in the following sexual activities?

Masturbation *(solitary or by partner)*:	**Intercourse *(anal or vaginal)*:**	**Oral sex:**
☐ 0 *Never*	☐ 0 *Never*	☐ 0 *Never*
☐ 1 *Once per week*	☐ 1 *Once per week*	☐ 1 *Once per week*
☐ 2 *2-4 times per week*	☐ 2 *2-4 times per week*	☐ 2 *2-4 times per week*
☐ 3 *5-10 times per week*	☐ 3 *5-10 times per week*	☐ 3 *5-10 times per week*
☐ 4 *More than 10 times per week*	☐ 4 *More than 10 times per week*	☐ 4 *More than 10 times per week*

DataFax #147 Plate #036 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

MALES ONLY ☐ *N/A (female patient); If N/A is checked, go to question 3b.*

3a. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Spontaneous daytime erections	☐	☐
2. Painful erections	☐	☐
3. Erection when sexually aroused	☐	☐
4. Difficulty getting an erection when sexually stimulated	☐	☐
5. Difficulty maintaining an erection to complete sexual act	☐	☐
6. Waking up from sleep with an erection	☐	☐
7. Requiring more stimuli than usual to achieve an erection	☐	☐
8. Requiring more stimuli than usual to maintain an erection	☐	☐
9. Decreased fullness of erection	☐	☐
10. Increased sensitivity of genitals upon physical stimulation	☐	☐
11. Decreased sensitivity of genitals upon physical stimulation	☐	☐
12. Orgasm	☐	☐
13. Ejaculation	☐	☐
14. Painful orgasm/ejaculation	☐	☐
15. Orgasm without ejaculation	☐	☐
16. Delay in achieving orgasm/ejaculation but eventually doing so	☐	☐
17. Inability to achieve orgasm/ejaculation	☐	☐
18. Orgasm without erection	☐	☐
19. Orgasm occurring during sleep	☐	☐
20. Genital pain during sexual contact	☐	☐
21. Orgasm/ejaculation occurring earlier than desired	☐	☐
22. Experiencing orgasm without sexual provocation *(spontaneously, except in sleep)*	☐	☐
23. Generally decreased intensity of orgasm	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

RUSH SEXUAL INVENTORY SCALE (RSI):
SECTION B - *Page 3 of 3*

End of Week 4

DataFax #147 Plate #037 Seq. #104

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

FEMALES ONLY ☐ *N/A (male patient)*

3b. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Increased sensitivity, other than pain, in breasts upon physical contact	☐	☐
2. Increased sensitivity of genitals, other than pain, upon physical contact	☐	☐
3. Pain in breasts upon physical contact	☐	☐
4. Pain in genitals upon physical contact	☐	☐
5. Decreased sensitivity in breasts upon physical contact	☐	☐
6. Decreased sensitivity in genitals upon physical contact	☐	☐
7. Inadequate swelling or vaginal lubrication during sexual arousal	☐	☐
8. Orgasm	☐	☐
9. Multiple orgasm	☐	☐
10. Difficulty achieving orgasm, but eventually being able to	☐	☐
11. Inability to achieve orgasm	☐	☐
12. Experiencing orgasm without sexual provocation *(spontaneously)*	☐	☐
13. Painful orgasm	☐	☐
14. Decreased intensity or orgasm	☐	☐
15. Involuntary vaginal contractions that prevent vaginal penetration	☐	☐
If Yes check one: ☐ *always* ☐ *intermittently*		
16. Physical pain during sexual activity	☐	☐

What was the first day of your last menstrual period: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) ☐ *Not Applicable*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 5

- Complete the following CRFs:

Page #	Form
106	Vital Signs / AE & Concomitant Medication / Study Medication Record
107-110	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
111	Addendum Hamilton Psychiatric Rating Scale for Depression

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 106)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 106)*. Review dosing instructions if indicated.

- Dispense Week 6's supply of study medication.

- Schedule patient for End of Week 6 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 5

All **End of Week 5** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	106	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	107	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	108	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	109	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	110	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	111	Addendum Hamilton Psychiatric Rating Scale for Depression

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 5

DataFax #147 Plate #021 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 5

DataFax #147 Plate #015 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Page 107

DataFax #147 Plate #016 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 5

DataFax #147 Plate #017 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

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16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #018 Seq. #105

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 5

DataFax #147 Plate #019 Seq. #105

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Principal Investigator _____ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal
- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General
- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms
- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping
- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:
- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 6

- Complete the following CRFs:

Page #	Form
112	Vital Signs / AE & Concomitant Medication / Study Medication Record
113-116	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
117	Addendum Hamilton Psychiatric Rating Scale for Depression
118-120	Montgomery - Asberg Depression Rating Scale (MADRS)
121	Clinical Global Impressions (CGI)
122	Patient Global Impressions (PGI)
123-125	SF-36 Health Survey
126-127	Kellner Symptom Questionnaire (KSQ)
128-129	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 112)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 112)*. Review dosing instructions if indicated.

- Dispense Week 7's supply of study medication.

- Schedule patient for End of Week 7 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 6

All **End of Week 6** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	112	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	113	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	114	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	115	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	116	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	117	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	118	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	119	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	120	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	121	Clinical Global Impressions (CGI)
☐	122	Patient Global Impressions (PGI)
☐	123	SF-36 Health Survey - *Page 1 of 3*
☐	124	SF-36 Health Survey - *Page 2 of 3*
☐	125	SF-36 Health Survey - *Page 3 of 3*
☐	126	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	127	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	128	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	129	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 6

DataFax #147 Plate #021 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 6

DataFax #147 Plate #015 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Page 113

DataFax #147 Plate #016 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

End of Week 6

DataFax #147 Plate #018 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

25-ITEM HAMD - *Page 4 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 6

DataFax #147 Plate #019 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (Site No.) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 6

DataFax #147 Plate #022 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 6

DataFax #147 Plate #025 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PATIENT GLOBAL IMPRESSIONS (PGI)

End of Week 6

DataFax #147 Plate #026 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

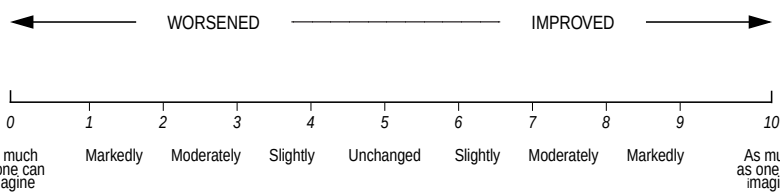
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 6

DataFax #147 Plate #027 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #028 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 6

DataFax #147 Plate #030 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 6

DataFax #147 Plate #031 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

KSQ - Continued

		Yes	No
47.	Thinking of death or dying	☐	☐
48.	Hot tempered	☐	☐
49.	Terrified	☐	☐
50.	Feelings of courage	☐	☐
51.	Enjoying yourself	☐	☐
52.	Breathing is difficult	☐	☐
53.	Parts of body numb or tingling	☐	☐
54.	Takes a long time to fall asleep	☐	☐
55.	Feeling hostile	☐	☐
56.	Infuriated	☐	☐
57.	Heart beating fast or pounding	☐	☐
58.	Depressed	☐	☐
59.	Jumpy	☐	☐
60.	Feeling like a failure	☐	☐
		True	**False**
61.	Not interested in things	☐	☐
		Yes	**No**
62.	Highly strung	☐	☐
		True	**False**
63.	Cannot relax	☐	☐
		Yes	**No**
64.	Panicky	☐	☐
65.	Pressure on head	☐	☐
66.	Blaming yourself	☐	☐
67.	Thoughts of ending your life	☐	☐
68.	Frightening thoughts	☐	☐
69.	Enraged	☐	☐

		Yes	No
70.	Irritated by other people	☐	☐
71.	Looking forward to the future	☐	☐
72.	Nauseated, sick to stomach	☐	☐
73.	Feeling that life is bad	☐	☐
74.	Upset bowels or stomach	☐	☐
75.	Feeling inferior to others	☐	☐
76.	Feeling useless	☐	☐
77.	Muscle pains	☐	☐
		True	**False**
78.	No unpleasant feelings in head or body	☐	☐
		Yes	**No**
79.	Headaches	☐	☐
80.	Feel like attacking people	☐	☐
81.	Shaking with anger	☐	☐
82.	Mad	☐	☐
83.	Feelings of goodwill	☐	☐
84.	Feel like crying	☐	☐
85.	Cramps	☐	☐
86.	Feeling that something bad will happen	☐	☐
87.	Wound up, uptight	☐	☐
88.	Get angry quickly	☐	☐
89.	Self-confident	☐	☐
90.	Resentful	☐	☐
91.	Feelings of hopelessness	☐	☐
92.	Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 6

DataFax #147 Plate #032 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 19APR99)

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DataFax #147 Plate #033 Seq. #106

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 7

- Complete the following CRFs:

Page #	Form
130	Vital Signs / AE & Concomitant Medication / Study Medication Record
131-134	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
135	Addendum Hamilton Psychiatric Rating Scale for Depression

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 130)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 130)*. Review dosing instructions if indicated.

- Dispense Week 8's supply of study medication.

- Schedule patient for End of Week 8 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 7

All **End of Week 7** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	130	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	131	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	132	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	133	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	134	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	135	Addendum Hamilton Psychiatric Rating Scale for Depression

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	159	Study Termination Report - Part 1

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 7

DataFax #147 Plate #021 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 7

DataFax #147 Plate #015 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #016 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 7

DataFax #147 Plate #017 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

End of Week 7

DataFax #147 Plate #018 Seq. #107

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 7

DataFax #147 Plate #019 Seq. #107

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Principal Investigator _____ ___ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 8

- Complete the following CRFs:

Page #	Form
136	Vital Signs / AE & Concomitant Medication / Study Medication Record
137	Electrocardiogram (ECG) / Pregnancy Test *(Note: Mail duplicate original ECG to Premier)*
138-141	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
142	Addendum Hamilton Psychiatric Rating Scale for Depression
143-145	Montgomery - Asberg Depression Rating Scale (MADRS)
146	Clinical Global Impressions (CGI)
147	Patient Global Impressions (PGI)
148-150	SF-36 Health Survey
151-152	Kellner Symptom Questionnaire (KSQ)
153-154	Social Adaptation Self-Evaluation Scale (SASS)
155-157	Rush Sexual Inventory Scale (RSI): Section B
158	DSM-IV 5-Axis Clinical Diagnosis
159	Study Termination - Part 1

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 136)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Draw safety laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*

- Check patient's Part 1 Dosing Diary and Study Medication Compliance *(Record on CRF page 136).* Collect Part 1 Dosing Diary.

- If patient qualifies for randomization into Part 2, obtain the next sequential Part 2 study medication box and record the randomization number (e.g., 5001) indicated on the box on all Part 2 CRF's for this patient. Give patient a Part 2 Dosing Diary and review Part 2 Dosing instructions.

- Dispense Week 9's supply of study medication.

- Schedule patient for End of Week 9 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 1

DataFax #147 Plate #500 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

END OF WEEK 8

All **End of Week 8** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	136	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	137	Electrocardiogram (ECG) / Pregnancy Test
☐	138	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	139	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	140	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	141	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	142	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	143	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	144	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	145	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	146	Clinical Global Impressions (CGI)
☐	147	Patient Global Impressions (PGI)
☐	148	SF-36 Health Survey - *Page 1 of 3*
☐	149	SF-36 Health Survey - *Page 2 of 3*
☐	150	SF-36 Health Survey - *Page 3 of 3*
☐	151	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	152	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	153	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	154	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	155	Rush Sexual Inventory Scale (RSI): Section B - *Page 1 of 3*
☐	156	Rush Sexual Inventory Scale (RSI): Section B - *Page 2 of 3*
☐	157	Rush Sexual Inventory Scale (RSI): Section B - *Page 3 of 3*
☐	158	DSM-IV 5-Axis Clinical Diagnosis
☐	159	Study Termination Report - Part 1

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 8

DataFax #147 Plate #021 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

DataFax #147 Plate #038 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

ELECTROCARDIOGRAM *(ECG)*

Date ECG Performed ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) Time ☐☐:☐☐ *hours* (*00:01 - 24:00*)

Date of last dose of study medication ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) Time ☐☐:☐☐ *hours* (*00:01 - 24:00*)

Are there any clinically significant changes noted from Screen ECG? ☐ *No* ☐ *Yes*

Note: Please mail a duplicate original Electrocardiogram (ECG) to PREMIER.

PREGNANCY TEST *(Serum)*

NOT DONE, Reason: ☐ *Male* ☐ *Surgically sterile* ☐ *Postmenopausal (>2 years)*

DONE, Result: ☐ *Negative* ☐ *Positive* ☐ *Inconclusive*

Note: If test is positive or inconclusive, subject should be removed from the study.

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 8

DataFax #147 Plate #015 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #016 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 8

DataFax #147 Plate #017 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #018 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 8

DataFax #147 Plate #019 Seq. #108

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Principal Investigator _____ **Country** US

ADDENDUM FOR HAMD

26. Somatic Symptoms-Gastrointestinal
- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General
- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms
- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms
- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:
- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping
- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:
- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation
- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 8

DataFax #147 Plate #022 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

DataFax #147 Plate #023 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

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Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 8

DataFax #147 Plate #025 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

CLINICAL GLOBAL IMPRESSIONS (CGI)

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PATIENT GLOBAL IMPRESSIONS (PGI)

End of Week 8

DataFax #147 Plate #026 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

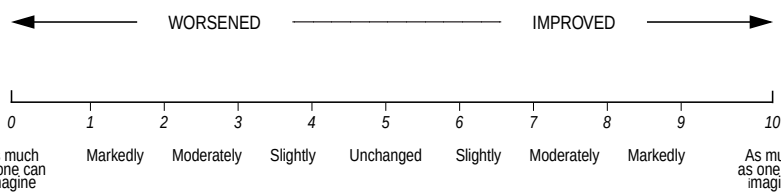
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

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Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 8

DataFax #147 Plate #027 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

DataFax #147 Plate #028 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Principal Investigator _____ ☐☐☐☐☐
Country US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

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Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 8

DataFax #147 Plate #030 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

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Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 8

DataFax #147 Plate #031 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐

Country US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 19APR99)

Reviewer's Initials: _____

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 8

DataFax #147 Plate #032 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 2 of 2*

End of Week 8

DataFax #147 Plate #033 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

RUSH SEXUAL INVENTORY SCALE (RSI):
SECTION B - ***Page 1 of 3***

End of Week 8

DataFax #147 Plate #035 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI

1. Rate each item as it applies in the PAST 4 WEEKS. For each item below, place a mark on the line where you would place yourself.

Example:

infrequent — *very frequent*

a. How frequently do you have pleasurable sexual thoughts?

infrequent — *very frequent*

b. Rate your ability to become sexually excited:

unable — *always able*

c. How frequently do you have desires to initiate sexual activity?

infrequent — *very frequent*

d. How often do you initiate sexual activity?

infrequent — *very frequent*

e. Rate your overall degree of sexual satisfaction attained:

low — *high*

2. How many times on average in the PAST 4 WEEKS did you engage in the following sexual activities?

Masturbation *(solitary or by partner)*:	**Intercourse *(anal or vaginal)*:**	**Oral sex:**
☐ *0 Never*	☐ *0 Never*	☐ *0 Never*
☐ *1 Once per week*	☐ *1 Once per week*	☐ *1 Once per week*
☐ *2 2-4 times per week*	☐ *2 2-4 times per week*	☐ *2 2-4 times per week*
☐ *3 5-10 times per week*	☐ *3 5-10 times per week*	☐ *3 5-10 times per week*
☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*

RSI: SECTION B - *Page 1 of 3*

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DataFax #147 Plate #036 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

MALES ONLY ☐ *N/A (female patient); If N/A is checked, go to question 3b.*

3a. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Spontaneous daytime erections	☐	☐
2. Painful erections	☐	☐
3. Erection when sexually aroused	☐	☐
4. Difficulty getting an erection when sexually stimulated	☐	☐
5. Difficulty maintaining an erection to complete sexual act	☐	☐
6. Waking up from sleep with an erection	☐	☐
7. Requiring more stimuli than usual to achieve an erection	☐	☐
8. Requiring more stimuli than usual to maintain an erection	☐	☐
9. Decreased fullness of erection	☐	☐
10. Increased sensitivity of genitals upon physical stimulation	☐	☐
11. Decreased sensitivity of genitals upon physical stimulation	☐	☐
12. Orgasm	☐	☐
13. Ejaculation	☐	☐
14. Painful orgasm/ejaculation	☐	☐
15. Orgasm without ejaculation	☐	☐
16. Delay in achieving orgasm/ejaculation but eventually doing so	☐	☐
17. Inability to achieve orgasm/ejaculation	☐	☐
18. Orgasm without erection	☐	☐
19. Orgasm occurring during sleep	☐	☐
20. Genital pain during sexual contact	☐	☐
21. Orgasm/ejaculation occurring earlier than desired	☐	☐
22. Experiencing orgasm without sexual provocation *(spontaneously, except in sleep)*	☐	☐
23. Generally decreased intensity of orgasm	☐	☐

Reviewer's Initials: _____

DataFax #147 Plate #037 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

FEMALES ONLY ☐ *N/A (male patient)*

3b. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Increased sensitivity, other than pain, in breasts upon physical contact	☐	☐
2. Increased sensitivity of genitals, other than pain, upon physical contact	☐	☐
3. Pain in breasts upon physical contact	☐	☐
4. Pain in genitals upon physical contact	☐	☐
5. Decreased sensitivity in breasts upon physical contact	☐	☐
6. Decreased sensitivity in genitals upon physical contact	☐	☐
7. Inadequate swelling or vaginal lubrication during sexual arousal	☐	☐
8. Orgasm	☐	☐
9. Multiple orgasm	☐	☐
10. Difficulty achieving orgasm, but eventually being able to	☐	☐
11. Inability to achieve orgasm	☐	☐
12. Experiencing orgasm without sexual provocation *(spontaneously)*	☐	☐
13. Painful orgasm	☐	☐
14. Decreased intensity or orgasm	☐	☐
15. Involuntary vaginal contractions that prevent vaginal penetration	☐	☐
If Yes check one: ☐ *always* ☐ *intermittently*		
16. Physical pain during sexual activity	☐	☐

What was the first day of your last menstrual period: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) ☐ *Not Applicable*

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

STUDY TERMINATION: DSM-IV 5-AXIS CLINICAL DIAGNOSIS

End of Week 8

DataFax #147 Plate #010 Seq. #108

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Principal Investigator _____ ☐☐☐☐☐ **Country** US

DSM-IV 5-AXIS CLINICAL DIAGNOSIS

AXIS	CODE	NAME
Axis I (DSM-IV)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
Axis II (DSM-IV)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
Axis III (ICD-9-CM)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____

Axis IV ***Please check all that applies:***

- ☐ 1 *Problems with primary support group*
- ☐ 2 *Problems related to the social environment*
- ☐ 3 *Educational problems*
- ☐ 4 *Occupational problems*
- ☐ 5 *Housing problems*
- ☐ 6 *Economic problems*
- ☐ 7 *Problems with access to health care services*
- ☐ 8 *Problems related to interaction with legal system/crime*
- ☐ 9 *Other psychosocial and environmental problems*

Specify: _____

COMMENTS: _____

Axis V Current Score: ☐☐☐

Extreme Mood reactivity present..... ☐ *No* ☐ *Yes*

Rejection sensitivity present..... ☐ *No* ☐ *Yes*

Initials or Signature: _____

PROTOCOL M/2020/0034

STUDY TERMINATION REPORT - PART 1

Pharmacia & Upjohn

STUDY TERMINATION REPORT - Instructions

Instructions to be placed facing each *Study Termination Report* question page (Modules 1 and 2)

DEFINITION OF STUDY TERMINATION REPORT

Study Termination Report refers to the end of study medication period. It is not meant for temporary withdrawal or for the end of follow-up or observation period.

- Check only one option for the patient disposition.
- Always refer back to the *Study Medication* record and double check the day of last study medication. This date must be in accordance with other visit dates (ie, not be before the first visit or after the last visits).
- **To radomize a patient to Part 2 and obtain a randomization number, assign the next numbered medication box to the patient. The number on the medication box for Part 2 is that patient's "Randomization" Number, (e.g. 5001)**
- If the patient did NOT complete the treatment period as defined in the study protocol, choose one primary reason for withdrawal. Try to find out what lies behind the withdrawal, eg, why a consent was withdrawn or a protocol violation happened. Do not enter that cause on this form, but keep it ready for review. Do not be too quick to enter "Lost to follow-up", patients sometimes return.
- Always choose the most severe reason. Example: If the patient withdrew the informed consent and had side effects that caused problems, check "Adverse event".
- Termination: The *Study Termination Report* page must be completed and submitted for all patients who were assigned study medication.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

STUDY TERMINATION REPORT - PART 1

End of Part 1

DataFax #147 Plate #039 Seq. #199

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Principal Investigator _____ ☐☐☐☐☐ **Country** US

*Choose **one** of the following alternatives to describe the patient disposition:*

☐ *Patient assigned open label Reboxetine treatment but did not take any*

☐ *Patient assigned open label Reboxetine treatment and took at least one dose, Date of last dose* ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Did patient complete 8 weeks of treatment?..... ☐ *No* ☐ *Yes*

If Yes, Did patient have ≥ 50% reduction in total 25-item HAMD score at Day 57 compared to Day 1 and CGI improvement of 1 or 2 *(very much improved or much improved)*?..... ☐ *No* ☐ *Yes*

25-item HAMD score at Day 57 ***(see CRF page xx)***?..... ☐☐

Will patient enter Part 2? ☐ *No* ☐ *Yes*

*If **Yes**, record patient randomization number from Part 2 medication box assigned to this patient:* ☐☐☐☐
(Also enter randomization number and Day 57 25-item HAMD score on the first page of Part 2 binder)

*If **No**, choose **one** primary reason for withdrawal:*

☐ 1 *Adverse event* → ***Fill in / update Adverse Event page***

☐ 2 *Protocol violation* → ***Explain in Comments section below***

☐ 3 *Consent withdrawn* → ***Explain in Comments section if necessary***

☐ 4 *Lost to follow-up*

☐ 5 *Failure to respond to Reboxetine according to protocol definition*

☐ 6 *Other, specify:* _____

COMMENTS

Investigator's Signature: _____

PROTOCOL M/2020/0034

END OF PART 1

If patient **IS** randomized into Part 2, please do the following:

- Remove the following case report forms and insert them into the appropriate sections in the Part 2 binder:
  - Adverse Event Forms
  - Serious Adverse Event Forms
  - Adverse Event Follow-up Forms
  - Concomitant Medication Forms
  - Exposure in Utero Form
- Record the 25-item HAMD total score at Day 57 on the first page of the Part 2 binder.

PROTOCOL M/2020/0034

ADVERSE EVENT REPORT FORMS

Report only one adverse event per form. If an event stops and later restarts, record the new occurrence on a new form and should be faxed into the Datafax system (1-888-272-7778).

Pharmacia & Upjohn

ADVERSE EVENT REPORT FORM - Instructions

DEFINITION OF AN ADVERSE EVENT

An adverse event (AE) is any untoward medical occurrence in a patient or trial subject administered a drug or biologic (medicinal product) or using a medical device; the event does not necessarily have a casual relationship with that treatment or usage.

Adverse Events include the following:

- All suspected adverse medication (device, etc.) reactions.
- All reactions from medication abuse, overdose, withdrawal, sensitivity, or toxicity.
- Apparently unrelated illness, including the worsening of a preexisting illness.
- Injury or accidents. Note that if a medical condition is known to have caused the injury or accident (e.g., a fall secondary to dizziness), the medical condition (dizziness) and the accident (fall) should be reported as two separate adverse events. The outcome of the accident (e.g., hip fracture secondary to the fall) should be recorded under Comments.
- Abnormalities in physiological testing or physical examination findings that require clinical intervention or further investigation (beyond ordering a repeat [confirmatory] test).
- Laboratory abnormalities that require clinical intervention or further investigation (beyond ordering a repeat [confirmatory] test) unless they are associated with an already reported clinical event. Laboratory abnormalities associated with a clinical event (e.g., elevated liver enzymes in a patient with jaundice) should be described under Comments on the report of the clinical event rather than listed as a separate adverse event.

- The standard source of AEs is investigator reporting of:
  1. All directly observed events.
  2. Events elicited from the trial subject by means of the general non-directive question, **"Since your last clinic visit have you had any health problems?"**
  3. Events spontaneously volunteered by the trial subject.
- **Enter all adverse events that begin at the time of the Day 1 evaluation and end with the final clinic visit (Week 32; Day 225). Adverse events that occur after the follow-up period that are believed to be related to the investigational medication should also be reported.**
- *(Not first visit)* Any change in intensity, seriousness (or frequency) should be reported by updating the *Adverse Event* page.
- A pre-existing condition should be reported as an adverse event when the condition increases in intensity, episodes increase in frequency during the adverse event reporting period, or becomes serious.

Pharmacia & Upjohn

ADVERSE EVENT REPORT FORM - Instructions

- Report only one adverse event per form. If an event stops and later restarts, record the new occurrence on a new form.
- **Adverse Event:** List the syndrome (rather than the symptoms) as precisely as possible and if applicable also indicate the location of the event (e.g., Migraine, left sided).
- **Start / Change Date:** Indicate the event's start date as the first appearance of this event during the study. Indicate the event's intensity, and if the event was serious. Indicate **ALL** changes in status of the same adverse event (e.g., increases and decreases in intensity). For instance, if diarrhea starts as moderate on the initial report, then becomes mild, indicate the date changed and the intensity change on the next line. Also indicate the seriousness status.
- **Intensity:** The following definition is used for intensity:

MILD	Does not interfere with patient's usual function
MODERATE	Interferes to some extent with patient's usual function
SEVERE	Interferes significantly with patient's usual function

- **Was event serious?:** An adverse event that meets one or more of the following criteria/outcomes is classified as serious:
  - Death
  - Life-threatening (i.e., immediate risk of death)
  - In-patient hospitalization or prolongation of existing hospitalization
  - Persistent or significant disability/incapacity (any sight-threatening event with ophthalmic products is a significant incapacity)
  - Permanent impairment of function or permanent damage to a body structure or requires intervention to prevent permanent impairment or damage
  - Congenital anomaly/birth defect
  - Any other adverse event that the investigator or company judges to be serious or which is defined as serious by the regulatory agency in the country in which the adverse event occurred.
- **In case of serious adverse event: A *Serious Adverse Event Report Form* must be completed in addition to this *Adverse Event* CRF. NOTE that Pharmacia & Upjohn monitor must be notified within 24 hours of awareness of the event by the investigator. Carefully read further instructions on the *Serious Adverse Event Report Form.***
- **Event continued from Adverse Event Report Form AEF#:** If more than one page is needed to report all changes for a single adverse event, then record the first page AEF# used in this field.
- **Action taken with study medication due to <u>this</u> event:** Any change made in study medication as a result of the adverse event. Check one box describing the action taken.
- **Outcome:** Record the **final** outcome of the event at the resolution of the adverse event during the study or at the end of the study (if event is continuing). If death occurred and an unassociated adverse event was unresolved, record the Outcome of the unassociated adverse event as "Not recovered".
- **Stop Date:** Record the date the event resolved, the date when the event resolved with sequelae or the date when the patient died. If the outcome is not recovered or unknown, do not enter stop date. Any resolution after the final visit will be recorded on the Adverse Event Follow-up.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 101

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF01

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 102

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF02

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 103

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes *If 'serious' fill in Serious Adverse Event form*	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF03

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 104

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF04

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 105

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF05

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 106

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF06

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 107

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF07

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 108

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF08

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 109

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF09

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 110

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.*)**

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF10

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 111

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF11

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 1 1 2

DataFax #147 Plate #042

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1☐☐

Start / Change Date (*y y y y m m d d*)	**Was event serious?** (*since last visit*) *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** (*since last visit*) *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*
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☐☐☐☐☐☐☐☐	☐	☐	☐

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

AEF12

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 113

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF13

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 114

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF14

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 115

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form **AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.*)**

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF15

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 116

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes *If 'serious' fill in Serious Adverse Event form*	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF16

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 117

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF17

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 118

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes *If 'serious' fill in Serious Adverse Event form*	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF18

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 119

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF19

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 120

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.*)**

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF20

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 121

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes *If 'serious' fill in Serious Adverse Event form*	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF21

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 122

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF22

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 1 2 3

DataFax #147 Plate #042

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1☐☐

Start / Change Date (*y y y y m m d d*)	**Was event serious?** (*since last visit*) *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** (*since last visit*) *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*
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Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

AEF23

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 124

DataFax #147 Plate #042

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (y y y y m m d d)	**Was event serious?** *(since last visit)* 0=No 1=Yes ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* 1=Mild 2=Moderate 3=Severe	**Action taken with study medication** 0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (y y y y m m d d)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
6=Not recovered *

(* **Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered*.**)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

AEF24

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 125

DataFax #147 Plate #042

Subject Number ___ - ____ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ____ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1__

Start / Change Date (*y y y y m m d d*)	**Was event serious?** (*since last visit*) *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** (*since last visit*) *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: ____ (*y y y y m m d d*)

Outcome (at stop date): ☐
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** ____ (*y y y y m m d d*)

AEF25

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

CONCOMITANT MEDICATION FORM

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 0 1

DataFax #147 Plate #043

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

CONCOMITANT MEDICATION FORM

Example

Date Started 1999 0303 (y y y y m m d d)

ASPIRIN *Medication Trade or Generic Name*

Date Stopped ____ **Ongoing at Final visit** X

200	MG	QID	PO	HEADACHE
Dose Amount	*Units*	*Frequency*	*Route*	**Reason for Use of Medication (Major Diagnosis)*

001

Date Started ____ (y y y y m m d d)

_____ *Medication Trade or Generic Name*

Date Stopped ____ **Ongoing at Final visit** ☐

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

002

Date Started ____ (y y y y m m d d)

_____ *Medication Trade or Generic Name*

Date Stopped ____ **Ongoing at Final visit** ☐

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

003

Date Started ____ (y y y y m m d d)

_____ *Medication Trade or Generic Name*

Date Stopped ____ **Ongoing at Final visit** ☐

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM01

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 302

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM02

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 0 3

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM03

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 304

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM04

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 305

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM05

Pharmacia & Upjohn
Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM

DURING STUDY

CM # 3 0 6

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.)
Subject's Initials ___ (F M L)
Date of Evaluation ___ (y y y y m m d d)

Randomization Number ___
Principal Investigator ___
Country US

CONCOMITANT MEDICATION FORM (Extra Form)

Concomitant Medication - Continued

Medication Trade or Generic Name	Date Started (y y y y m m d d)	Date Stopped (y y y y m m d d)	Ongoing at Final visit	
Dose Amount	Units	Frequency	Route	*Reason for Use of Medication (Major Diagnosis)
Medication Trade or Generic Name	Date Started (y y y y m m d d)	Date Stopped (y y y y m m d d)	Ongoing at Final visit	
Dose Amount	Units	Frequency	Route	*Reason for Use of Medication (Major Diagnosis)
Medication Trade or Generic Name	Date Started (y y y y m m d d)	Date Stopped (y y y y m m d d)	Ongoing at Final visit	
Dose Amount	Units	Frequency	Route	*Reason for Use of Medication (Major Diagnosis)
Medication Trade or Generic Name	Date Started (y y y y m m d d)	Date Stopped (y y y y m m d d)	Ongoing at Final visit	
Dose Amount	Units	Frequency	Route	*Reason for Use of Medication (Major Diagnosis)

Protocol M/2020/0034 (FINAL 19APR99)

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: ___ **Date:** ___ (y y y y m m d d)

CM06

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 307

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM07

Pharmacia & Upjohn
Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 0 8

DataFax #147 Plate #044

Subject Number ____ - ________ (Site No.)
Subject's Initials ___ (F M L)
Date of Evaluation ________ (y y y y m m d d)

Randomization Number ________
Principal Investigator ________
Country US

Concomitant Medication - Continued

Date Started (y y y y m m d d)
Date Stopped
Ongoing at Final visit

Medication Trade or Generic Name

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

Date Started (y y y y m m d d)
Date Stopped
Ongoing at Final visit

Medication Trade or Generic Name

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

Date Started (y y y y m m d d)
Date Stopped
Ongoing at Final visit

Medication Trade or Generic Name

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

Date Started (y y y y m m d d)
Date Stopped
Ongoing at Final visit

Medication Trade or Generic Name

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

*** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use**

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: ________________ Date: ________ (y y y y m m d d)

CM08

CONCOMITANT MEDICATION FORM *(Extra Form)*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 309

DataFax #147 Plate #044

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM09

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 0

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM10

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 1

DataFax #147 Plate #044

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ____

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM11

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 2

DataFax #147 Plate #044

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM12

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 3

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM13

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 4

DataFax #147 Plate #044

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

Date Stopped ____ ***Ongoing at Final visit*** ☐

_____ *Medication Trade or Generic Name*

_____ *Dose Amount* _____ *Units* _____ *Frequency* _____ *Route* _____ **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM14

Pharmacia & Upjohn

Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 5

DataFax #147 Plate #044

Subject Number ____ - ________ (Site No.)
Subject's Initials ___ (F M L)
Date of Evaluation ________ (y y y y m m d d)

Randomization Number ____
Principal Investigator ________ _____
Country US

Concomitant Medication - Continued

___ Medication Trade or Generic Name
Date Started (y y y y m m d d)
Date Stopped (y y y y m m d d)
Ongoing at Final visit ☐

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

___ Medication Trade or Generic Name
Date Started (y y y y m m d d)
Date Stopped (y y y y m m d d)
Ongoing at Final visit ☐

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

___ Medication Trade or Generic Name
Date Started (y y y y m m d d)
Date Stopped (y y y y m m d d)
Ongoing at Final visit ☐

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

___ Medication Trade or Generic Name
Date Started (y y y y m m d d)
Date Stopped (y y y y m m d d)
Ongoing at Final visit ☐

Dose Amount | Units | Frequency | Route | *Reason for Use of Medication (Major Diagnosis)

*** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use**

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: ________ **Date:** ________ (y y y y m m d d)

CM15

CONCOMITANT MEDICATION FORM *(Extra Form)*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 6

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM16

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 7

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM17

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 8

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM18

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 3 1 9

DataFax #147 Plate #044

Subject Number ___ - ____ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ____ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ____ (y y y y m m d d)

_____ **Date Stopped** ____ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

_____ _____ _____ _____ _____

Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ____ (y y y y m m d d)

CM19

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM DURING STUDY

CM # 320

DataFax #147 Plate #044

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

Concomitant Medication - Continued

CONCOMITANT MEDICATION FORM *(Extra Form)*

___ **Date Started** ___ (y y y y m m d d)

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

Protocol M/2020/0034 (FINAL 19APR99)

___ **Date Started** ___

Date Stopped ___ ***Ongoing at Final visit*** ☐

_____
Medication Trade or Generic Name

_____ _____ _____ _____ _____
Dose Amount *Units* *Frequency* *Route* **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: _____ **Date:** ___ (y y y y m m d d)

CM20

PROTOCOL M/2020/0034

SERIOUS ADVERSE EVENT REPORT FORMS

Pharmacia & Upjohn

SERIOUS ADVERSE EVENT REPORT FORM
Patient / Serious Adverse Event Information - - Instructions

To be completed by the Investigator:

Please print using all **CAPITAL (BLOCK)** letters.

Dates: Record all dates as completely as possible in yyyy / mm / dd format.

Example:

1	9	9	8	0	5	1	3
y	*y*	*y*	*y*	*m*	*m*	*d*	*d*

- **Patient Information:** All information in this section **MUST** be entered.
- **Serious Adverse Event:** This report is only for those adverse events that meet the seriousness criteria. Please use the same terminology used on the Case Report Form (CRF) for *Adverse Event.* Review the protocol for the definition of an adverse event, the criteria used to determine if the adverse event is serious, and how this should be reported **(ie, if a set of symptoms and/or signs appear to constitute a diagnosis or syndrome, list only the diagnosis; if these do not constitute a diagnosis or syndrome, then list each adverse event separately).**
- **Onset Date of Serious Adverse Event:** Indicate the date of the earliest sign/symptom related to the serious adverse event.
- **Date Event became Serious:** Indicate the date that the event was determined to meet the Seriousness Criteria.
- **Recovery Date of Serious Adverse Event:** Indicate the date of recovery from this serious adverse event.
- **Seriousness Criteria:** Check all that apply, but at least one box should be checked.
- **Investigator Summary of the Serious Adverse Event and/or Comments:** Enter only relevant information/ comments regarding the serious adverse event. Include related signs and symptoms in chronological order. Attach a separate sheet if necessary.
- **Relevant tests/Lab data, including dates:** Include any laboratory or other data (eg, X-ray, ECG, MRI findings) that are relevant or related to the serious adverse event being reported. Attach a separate sheet if necessary.
- **Relevant Medical History:** All relevant pre-existing and concomitant medical conditions (including allergies, presence and site of metastases in cancer patients, relevant surgeries) should be listed in this section.
- **Intervention / Management of the Serious Adverse Event:** If the event required intervention, check “Yes” and briefly describe medications, surgery, etc. performed.
- **Outcome on Day of Report:** Record outcome as known at the time of this report
  If death occurred due to another unassociated adverse event, check “Not recovered”.
  If condition is chronic or stable, check “Not recovered” and check the “Yes” box.
  If patient is not recovered, and the condition is not considered chronic or stable, check “Not recovered” and “No”.
- **Death Information:** Provide all relevant information on date of death, cause of death, and autopsy if known.

Pharmacia & Upjohn

SERIOUS ADVERSE EVENT REPORT FORM
Study & Concomitant Medication Information - Instructions

These sections must be completed by the Investigator:

- **Study Medication:** Enter the name of the study medication used in this protocol. For blinded studies, please enter "Blinded Study Medication" if this is not preprinted. In the event that the protocol has multiple study medications, please list all of them if not preprinted. **DO NOT BREAK THE BLINDING CODE just to complete this form.**

- **Relevant Concomitant Medication(s):** Enter only those concomitant medications that the patient was taking around the time of the serious adverse event that the investigator assesses to be relevant to the serious adverse event. Enter the **GENERIC** name for each relevant concomitant medication. **DO NOT include medications used to treat the event.**

The following explanations apply to both study and concomitant medications:

- **Dose Amount:** Indicate the amount of medication in each dose.

- **Units:** Indicate the unit of measurement of the dose (e.g., mg, I.U., mg/kg, etc.).

- **Frequency:** Indicate the number of doses per unit of time (e.g., BID, TID, WEEKLY, etc.), or rate of infusion (e.g., 6 hrs, 2 hrs, continuous, etc.)

- **Route:** (e.g., IV = intravenously, PO = per oral, INTRATHECAL, INTRAVESICLE, etc.)

- **Date of first dose:** Indicate the date of the first administration of the medication.

- **Date of last dose before the event:** If the patient has stopped taking this medication, enter the date the last dose was taken. If medication continues, draw a line through the stop date.

- **Is there a reasonable possibility that the serious adverse event is related to this medication?:** The investigator is **REQUIRED** to answer this question for study medications. The investigator should review the protocol for further direction on how to assess relationship to study medication.

The following explanations apply to study medications only:

- **P&U Product:** If the blind has been broken, check "Yes" or "No" as appropriate. If the blind has not been broken, check "NA/unknown".

- **Action Taken with Study Medication:** Each possible action taken with study medication is denoted by a numeric code. Select one and enter the appropriate code:

  ***0** = None* ***1** = Dose reduced* ***2** = Dose increased*
  ***3** = Drug permanently withdrawn* ***4** = Drug temporarily withdrawn*

- **Did event abate after stopping medication?:** If study medication was discontinued, indicate whether the serious adverse event abated (lessened or decreased). ***No*** means that the study medication was discontinued and the event did not abate. ***Yes*** means that the study medication was discontinued and the event abated. ***NA*** means that the patient is continuing to receive study medication.

- **Did event reappear after reintroducing study medication?:**
  Answer ***No:*** If the study medication was discontinued for any period of time and then restarted to find out if the event would recur, and the event did not recur.
  Answer ***Yes:*** If the study medication was reintroduced and the event reappeared.
  Answer ***NA:*** If study medication was either **NOT** discontinued or **NOT** reintroduced.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SERIOUS ADVERSE EVENT REPORT FORM - *Page 1 of 3*

SAEF# 2 0 1

DataFax #147 Plate #045

(SAEF # should be assigned in an increasing order starting with 01)

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT INFORMATION *(Use separate sheet for each event)*

Date of Birth (*y y y y m m d d*)	Sex	Height	Weight
☐☐☐☐ ☐☐ ☐☐	☐ *1 Male* ☐ *2 Female*	☐☐☐.☐ ☐ *1 cm* ☐ *2 in*	☐☐☐.☐ ☐ *1 kg* ☐ *2 lb*

SERIOUS ADVERSE EVENT INFORMATION

Serious Adverse Event: _____

Onset Date of Serious Adverse Event ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Date Event became Serious ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Recovery Date of Serious Adverse Event ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Seriousness Criteria *(Check all that apply)*

- ☐ *1 Death*
- ☐ *2 Life-threatening (ie. immediate risk of death)*
- ☐ *3 In-patient hospitalization/prolongation of existing hospitalization*
- ☐ *4 Persistent or significant disability/incapacity*
- ☐ *5 Congenital anomaly/birth defect*
- ☐ *6 Other medically relevant condition judged/defined as serious*

Investigator Summary of the Serious Adverse Event and/or Comments:

Relevant Tests / Lab data, including dates

Relevant Medical History

Intervention / Management of Serious Adverse Event

- ☐ *0 No*
- ☐ *1 Yes* → *describe:* _____

Outcome on Day of Report

- ☐ *1 Recovered* → *enter recovery date above*
- ☐ *2 Recovered with sequelae* → *enter recovery date above*

Specify: _____

- ☐ *3 Death* → *complete Death Information section*
- ☐ *4 Unknown*
- ☐ *6 Not recovered* → *Chronic?* ☐ *0 No* ☐ *1 Yes*

Death Information

Date of Death: ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Cause of Death: _____

Autopsy? ☐ *0 No* ☐ *1 Yes* → *(attach copy of report if available)*

This section for Pharmacia & Upjohn use only

Database No.:

Local Reference No.:

Investigator's Signature: _____ **Date:** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

SAEF1

SERIOUS ADVERSE EVENT FORM - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SERIOUS ADVERSE EVENT REPORT FORM - *Page 2 of 3*

SAEF# 2 0 1

DataFax #147 Plate #046

(SAEF # should be assigned in an increasing order starting with 01)

Subject Number ___ - ____ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ____ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

STUDY MEDICATION(S)

Part 1 ☐ **Study Medication**

P & U Product? ☐ 0 No ☒ 1 Yes ☐ 2 NA/unknown

Blind broken ☐ 0 No ☐ 1 Yes ☒ 2 NA/unknown

REBOXETINE (*Generic Name*)

Depression		**mg**	**BID**	**Oral**
Indication for use	*Dose Amount*	*Units*	*Frequency*	*Route of Admin.*

Date of first dose ____ (*y y y y m m d d*)

Date of last dose before the event ____ (*y y y y m m d d*)

Action taken with study medication *(enter code*)* ☐

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Did event abate after stopping medication? ☐ 0 No ☐ 1 Yes ☐ 2 NA

Did event reappear after reintroducing medication? ☐ 0 No ☐ 1 Yes ☐ 2 NA

Part 2 ☐ **Study Medication**

P & U Product? ☐ 0 No ☐ 1 Yes ☒ 2 NA/unknown

Blind broken ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Blinded Study Medication (*Generic Name*)

Depression		**mg**	**BID**	**Oral**
Indication for use	*Dose Amount*	*Units*	*Frequency*	*Route of Admin.*

Date of first dose ____ (*y y y y m m d d*)

Date of last dose before the event ____ (*y y y y m m d d*)

Action taken with study medication *(enter code*)* ☐

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Did event abate after stopping medication? ☐ 0 No ☐ 1 Yes ☐ 2 NA

Did event reappear after reintroducing medication? ☐ 0 No ☐ 1 Yes ☐ 2 NA

***Code of Action Taken:** *0 = None 1 = Dose reduced 2 = Dose increased 3 = Drug permanently withdrawn 4 = Drug temporarily withdrawn*

This section for Pharmacia & Upjohn use only

Database No.:

Local Reference No.:

Investigator's Signature: _____ **Date:** ____ (*y y y y m m d d*)

SAEF2

SERIOUS ADVERSE EVENT FORM - *Page 2 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn

Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

SERIOUS ADVERSE EVENT REPORT FORM *- Page 3 of 3*

SAEF# 2 0 1

DataFax #147 Plate #047

(SAEF # should be assigned in an increasing order starting with 01)

Subject Number ☐☐ - ☐☐☐☐ (Site No.) Subject's Initials ☐☐☐ (F M L) Date of Evaluation ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ Principal Investigator ____________ ☐☐☐☐☐ Country US

RELEVANT CONCOMITANT MEDICATION(S) *(use additional pages in the "Extra Forms" section if necessary)*

Generic Name ____________________ P & U Product? ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use ______ Dose Amount ______ Units ______ Frequency ______ Route of Admin. ______

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d) Date of last dose before the event ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Generic Name ____________________ P & U Product? ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use ______ Dose Amount ______ Units ______ Frequency ______ Route of Admin. ______

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d) Date of last dose before the event ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Generic Name ____________________ P & U Product? ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use ______ Dose Amount ______ Units ______ Frequency ______ Route of Admin. ______

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d) Date of last dose before the event ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

This section for Pharmacia & Upjohn use only
Database No.:
Local Reference No.:

Investigator's Signature: ____________________ Date: ☐☐☐☐☐☐☐☐ (y y y y m m d d)

SAEF3

SERIOUS ADVERSE EVENT FORM - Page 3 of 3

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

ADVERSE EVENT FOLLOW-UP REPORT

(As Needed)

Please use this form only to report the course of an unresolved Adverse Event (AE) from the time of the final study visit until the event resolves or is determined to be chronic or stable. Case report forms should be faxed to the DataFax system (1-888-272-7778) upon completion.

Pharmacia & Upjohn

ADVERSE EVENT FOLLOW-UP - Instructions

Please use this form only to report the course of an unresolved Adverse Event (AE) from the time of the final study visit until the event resolves or is determined to be chronic or stable. Case report forms should be faxed to the **DataFax system (1-888-272-7778)** upon completion.

Follow all adverse events which are serious or possibly related to study medication.

- **Adverse Event:** Report the same term as used on the original *Adverse Event* page.
- **AEF# where adverse event was originally reported:** Record the AEF# used to report this adverse event originally.
- **Outcome:** Record the outcome to date.
- **Stop Date:** Record the date the event resolved, the date when the event resolved with sequelae or the date when the patient died. If the outcome is not recovered or unknown, do not enter stop date.
- **Is the event chronic or stable?** Answer this question if the outcome is not recovered. If the answer to this question is No, continue to follow the adverse event using additional Adverse Event Follow-up pages until the event resolves or becomes chronic or stable.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FOLLOW-UP REPORT

AEFU # 401

DataFax #147 Plate #048

(AEFU# should be assigned in increasing order starting with 01)

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Report** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Please use the same terminology to describe the event as used on the *Adverse Event* page.

Adverse Event: _____

Record the AEF# of the AE page where adverse event was originally reported: **AEF #** 1☐☐

Date of follow-up: ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Outcome:

☐ *1 Recovered*
☐ *2 Recovered with sequelae* → **Stop date:** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
☐ *3 Death*
☐ *4 Unknown*
☐ *5 Lost to follow-up*
☐ *6 Not recovered* → Is event chronic or stable? ☐ *1 Yes*
☐ *0 No* → ***Continue to follow patient until the event resolves or becomes chronic or stable***

ADVERSE EVENT FOLLOW-UP REPORT

Protocol M/2020/0034 (FINAL 19APR99)

Initials or Signature: _____

AEFU

PROTOCOL M/2020/0034

EXPOSURE IN UTERO

(As Needed)

Case report form should be faxed to the DataFax system (1-888-272-7778) upon completion.

Pharmacia & Upjohn

SERIOUS ADVERSE EVENT REPORT FORM
Exposure in Utero - Instructions

Complete and send this form only if applicable.
For multiple pregnancies, complete one form for each fetus/infant.

- **Type of Report:** If the exposure in utero is being reported after there is an outcome of the pregnancy check *retrospective to birth*. If the exposure in utero is being reported while pregnancy continues select *prospective to birth*.

- **Date of conception, or estimated date of conception:** Provide an estimate (eg, by ultrasound) of the date of conception.

- **Date of outcome of pregnancy:** Enter the date that pregnancy ended.

- **Relevant medical history related to pregnancy:** Indicate in this section any maternal health problems and medications, smoking and alcohol use during this pregnancy, previous pregnancies and outcomes, family history of congenital anomaly and genetic diseases.

- **Gestational period at time of initial exposure:** Provide an estimate of the duration of pregnancy at the time of initial exposure to study medication and indicate whether it is weeks, months or which trimester by checking one of the three choices.

EXAMPLE; | 0 | 3 |

☐ 1 *Weeks*
☐ 2 *Month*
☒ 3 *Trimester*

- **Outcome of pregnancy:** Select all that apply. A *full term live birth* is a live birth at 37 or more weeks of gestation, a *premature live birth* is a live birth at less than 37 weeks of gestation, a *stillbirth* is the delivery of a dead child, also known as fetal death, a *miscarriage/abortion* is the premature expulsion from the uterus of the products of conception, the embryo, or of a non-viable fetus (less than 20 weeks gestation).

- **Any perinatal problems:** If yes, specify any maternal problems that may have occurred between 28 weeks of gestation and 4 weeks after birth (eg, polyhydramnios, abruptio placenta, placenta previa, postpartum hemorrhage, etc.)

- **Outcome of newborn:** Provide APGAR scores at 1, 5, and 10 minutes. Also indicate whether infant was normal or had a congenital or other anomaly and specify.

- **Newborn Information:** Enter information on sex, weight, length, and gestational age at birth or other outcome in this section.

- **Additional Information/Comments:** If necessary, provide additional maternal or infant information, here.

Pharmacia & Upjohn

Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

EXPOSURE IN UTERO DURING STUDY

Seq.# 4 0 1

(Seq. # should be assigned in increasing order starting with 01)

DataFax #147 Plate #049

Subject Number ___ - ___ *Site No.*

Subject's Initials ___ *F M L*

Date of Evaluation ___ *y y y y m m d d*

Randomization Number ____

Principal Investigator _____ ____

Country US

EXPOSURE IN UTERO

Type of report
- ☐ 1 *Retrospective to birth*
- ☐ 2 *Prospective to birth*

First day of last menstrual period ___ *y y y y m m d d*

Date of conception, or estimated date of conception ___ *y y y y m m d d*

Date of outcome of pregnancy ___ *y y y y m m d d*

Relevant medical history related to pregnancy:

Gestational period at time of initial exposure: ___
- ☐ 1 *Weeks*
- ☐ 2 *Month*
- ☐ 3 *Trimester*

Outcome of pregnancy
- ☐ 1 *Full term live birth*
- ☐ 2 *Premature live birth*
- ☐ 3 *Stillbirth*
- ☐ 4 *Congenital anomaly*
- ☐ 5 *Neonatal death*
- ☐ 6 *Miscarriage/spontaneous abortion*
- ☐ 7 *Induced / elective abortion*

Any perinatal problems?
- ☐ 0 *No*
- ☐ 1 *Yes, Specify:* _____

Outcome of newborn:

APGAR score at 1 minute ___

APGAR score at 5 minutes ___

APGAR score at 10 minutes ___
- ☐ 0 *Normal*
- ☐ 1 *Congenital anomaly, Specify:* _____
- ☐ 2 *Other anomaly, Specify:* _____

Newborn Information:

Sex:
- ☐ 1 *Male*
- ☐ 2 *Female*

Weight at birth: ____ *grams*

Length at birth: ___ .
- ☐ 1 *cm*
- ☐ 2 *in*

Gestational age: ___ *weeks*

Additional Information / Comments:

This section for Pharmacia & Upjohn use only

Database No.:

Local Reference No.:

Investigator's Signature: _____ **Date:** ___ *y y y y m m d d*

EXPOUTRO

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

EXTRA FORMS

Pharmacia & Upjohn

Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

CONCOMITANT MEDICATION FORM ***(Extra Form)*** DURING STUDY

DataFax #147 Plate #044

CM # 3

NOTE: If extra form is used, continue numbering consecutive pages (i.e. CM#) and medication line numbers in sequential order.

Subject Number ______ - ______ (Site No.)

Subject's Initials F M L

Date of Evaluation y y y y m m d d

Randomization Number ______

Principal Investigator ______

Country US

Concomitant Medication - Continued

Date Started y y y y m m d d

Date Stopped ______ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

Dose Amount | *Units* | *Frequency* | *Route* | **Reason for Use of Medication (Major Diagnosis)*

Date Started y y y y m m d d

Date Stopped ______ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

Dose Amount | *Units* | *Frequency* | *Route* | **Reason for Use of Medication (Major Diagnosis)*

Date Started y y y y m m d d

Date Stopped ______ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

Dose Amount | *Units* | *Frequency* | *Route* | **Reason for Use of Medication (Major Diagnosis)*

Date Started y y y y m m d d

Date Stopped ______ ***Ongoing at Final visit*** ☐

Medication Trade or Generic Name

Dose Amount | *Units* | *Frequency* | *Route* | **Reason for Use of Medication (Major Diagnosis)*

**** The same terminology as recorded on the Medical History or Adverse Event page(s) should be used to describe the reason for use***

COMMENTS *(Record the line number for each comment):*

NOTE: ***The Concomitant medication Form should be checked for completeness, signed and dated by the Investigator when the patient leaves the study.***

Investigator's Signature: ______ **Date:** y y y y m m d d

CMEX

CONCOMITANT MEDICATION FORM (Extra Form)

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADVERSE EVENT FORM DURING STUDY

AEF# 1

DataFax #147 Plate #042

NOTE: If extra page is used, continue numbering consecutive pages (i.e. AEF#) in sequential order.

Subject Number - *Site No.* **Subject's Initials** *F M L* **Date of Evaluation** *y y y y m m d d*

Randomization Number **Principal Investigator** _____ **Country** US

Read the instructions and definitions on instruction page before completing this page. Report only ONE event per page.

Adverse Event: _____

☐ *Initial Report* ☐ *Event continued from Adverse Event Form* ***AEF #*** 1

Start / Change Date	**Was event serious?** *(since last visit)* *0=No 1=Yes* ***If 'serious' fill in Serious Adverse Event form***	**Intensity** *(since last visit)* *1=Mild 2=Moderate 3=Severe*	**Action taken with study medication** *0=None 1=Dose reduced 2=Dose increased 3=Drug permanently withdrawn 4=Drug temporarily withdrawn*
y y y y m m d d			

Fill in stop date, outcome, and relationship when event resolves or when subject leaves the study.

Stop date: *y y y y m m d d*

Outcome (at stop date):
1=Recovered
2=Recovery with sequelae
3=Death
4=Unknown
*6=Not recovered **

(***Fill in the *Adverse Event Follow-up form* for serious or possibly related events which are *Not recovered.***)

Relationship: Is there a reasonable possibility that this event is related to the study medication? ☐ *No* ☐ *Yes*

COMMENTS:

NOTE: ***The Adverse Event page should be signed and dated by the Investigator when the event outcome has been assessed.***

Investigator's Signature: _____ **Date:** *y y y y m m d d*

AEFEX

ADVERSE EVENT FORM

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn

Protocol M/2020/0034
Principal Monitor: Saeeduddin Ahmed, M.D.

SERIOUS ADVERSE EVENT REPORT FORM - *Page 3 of 3 (Extra Form)*

SAEF# 2

DataFax #147 Plate #050

(SAEF # should be assigned in an increasing order starting with 01)

Subject Number ☐☐ - ☐☐☐☐ (Site No.)   Subject's Initials ☐☐☐ (F M L)   Date of Evaluation ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐   Principal Investigator ________ ☐☐☐☐☐   Country US

RELEVANT CONCOMITANT MEDICATION(S) *(use additional pages if necessary)*

Generic Name

________ **P & U Product?** ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use | *Dose Amount* | *Units* | *Frequency* | *Route of Admin.*

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d)   **Date of last dose before the event** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Generic Name

________ **P & U Product?** ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use | *Dose Amount* | *Units* | *Frequency* | *Route of Admin.*

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d)   **Date of last dose before the event** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

Generic Name

________ **P & U Product?** ☐ 0 No ☐ 1 Yes ☐ 2 NA/unknown

Indication for use | *Dose Amount* | *Units* | *Frequency* | *Route of Admin.*

Date of first dose ☐☐☐☐☐☐☐☐ (y y y y m m d d)   **Date of last dose before the event** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Is there a reasonable possibility that the serious event is related to this medication? ☐ 0 No ☐ 1 Yes

This section for Pharmacia & Upjohn use only   **Database No.:**
Local Reference No.:

Investigator's Signature: ________   **Date:** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

SAEF3X

SERIOUS ADVERSE EVENT FORM - *Page 3 of 3*

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

Hamilton Psychiatric Rating Scale for Depression (25-item) - Unscheduled Visit

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

UNSCHEDULED

Seq. # ☐☐☐

DataFax #147 Plate #051

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

☐ 0 *Absent*
☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
☐ 4 *Extreme symptoms - complete withdrawal*
☐ *Can't rate*

2. Distinct quality of mood

☐ 0 *No distinct qualities*
☐ 1 *Mild or moderate (slightly different)*
☐ 2 *Severe (definitely different)*
☐ *Can't rate*

3. Lack of reactivity

☐ 0 *Reactive mood (mood varies according to situation)*
☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
☐ *Can't rate*

4. Diurnal variation

☐ 0 *No variation in mood*
☐ 1 *Mild variation between a.m. and p.m.*
☐ 2 *Definite variation between a.m. and p.m.*
☐ *Can't rate*

5. Worthlessness

☐ 0 *Not present*
☐ 1 *Mild feelings of low self-esteem evident only from questioning*
☐ 2 *Feelings of worthlessness*
☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good at all." "Inferior to all others.")*
☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
☐ *Can't rate*

6. Guilt

☐ 0 *Absent*
☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
☐ 4 *Delusional guilt, with hallucinations*
☐ *Can't rate*

HAMD1

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 2 of 4*** UNSCHEDULED

Seq. # ☐☐☐

DataFax #147 Plate #052

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

HAMD2

25-ITEM HAMD - *Page 2 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

UNSCHEDULED

Seq. # ☐☐☐

DataFax #147 Plate #053

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

25-ITEM HAMD - *Page 3 of 4*

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

HAMD3

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

UNSCHEDULED

Seq. # ☐☐☐

DataFax #147 Plate #054

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

HAMD4

25-ITEM HAMD - *Page 4 of 4*

Protocol M/2020/0034 (FINAL 19APR99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)*** UNSCHEDULED

Seq. # ☐☐☐

DataFax #147 Plate #055

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____ ADDHAMD

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 19APR99)

PROTOCOL M/2020/0034

END OF PART 1

<u>If patient **IS** randomized into Part 2, please do the following:</u>

- Remove the following case report forms and insert them into the appropriate sections in the Part 2 binder:
    - Adverse Event Forms
    - Serious Adverse Event Forms
    - Adverse Event Follow-up Forms
    - Concomitant Medication Forms
    - Exposure in Utero Form
- Record the 25-item HAMD total score at Day 57 on the first page of the Part 2 binder.

PROTOCOL M/2020/0034

PART 2

Subject Number: ☐☐ - ☐☐☐☐
Site No.

Randomization Number: ☐☐☐☐

25-item HAMD score on End of Week 8 (Day 57) = ☐☐
(Part 1 Binder, CRF page 141)

The following case report forms should be removed from the Part 1 binder and inserted into the appropriate sections in the Part 2 binder:

- Adverse Event Forms
- Serious Adverse Event Forms
- Adverse Event Follow-up Forms
- Concomitant Medication Forms
- Exposure in Utero Form
- Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - Unscheduled Visit
- Addendum Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - Unscheduled Visit

PROTOCOL M/2020/0034

PART 2: DATAFAX VISIT MAP

Schedule of CRF Pages to be Completed at Each Patient Assessment

Plate No.	Form Title	Study Period	Scheduled Visits												FINAL
			End of Week												
			9	10	11	12	13	14	15	16	20	24	28	32	
		Seq. #	209	210	211	212	213	214	215	216	220	224	228	232	299
10	DSM-IV 5-Axis Clinical Diagnosis													188	
15-18	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - (4 pages)		2-5	9-12	28-31	35-38	54-57	61-64	80-83	87-90	109-112	128-131	147-150	167-170	
19	Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)*		6	13	32	39	58	65	84	91	113	132	151	171	
21	Vital Signs / AE & Concomitant Medication / Study Medication Record		1	8	27	34	53	60	79	86	108	127	146	165	
22-24	Montgomery-Asberg Depression Rating Scale (MADRS) - (3 pages)			15-17		41-43		67-69		93-95	115-117	134-136	153-155	173-175	
25	Clinical Global Impressions (CGI)			18		44		70		96	118	137	156	176	
26	Patient Global Impressions (PGI)			19		45		71		97	119	138	157	177	
27-29	SF-36 Health Survey (3 pages)			20-22		46-48		72-74		98-100	120-122	139-141	158-160	178-180	
30-31	Kellner Symptoms Questionnaire (KSQ) (2 pages)			23-24		49-50		75-76		101-102	123-124	142-143	161-162	181-182	
32-33	Social Adaptation Self-evaluation Scale (SASS) (2 pages)			25-26		51-52		77-78		103-104	125-126	144-145	163-164	183-184	
35-37	Rush Sexual Inventory Scale (RSI): Section B (3 pages)									105-107				185-187	
38	Electrocardiogram (ECG) / Pregnancy Test													166	
40	MDD Relapse Based on 25-item HAMD Scale		7	14	33	40	59	66	85	92	114	133	152	172	
41	Study Termination Report - Part 2														189
42	Adverse Event Form														
43-44	Concomitant Medication Form (2 pages)														
45-47	Serious Adverse Event Form (3 pages)														
48	Adverse Event Follow-up Report														
49	Exposure in Utero														
50	Serious Adverse Event Form - *Page 3 of 3 (Extra Form)*														
51-54	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) (4 pages) - Unscheduled Visit														
55	Addendum for Hamilton Psychiatric Rating Scale for Depression (*Includes additional symptoms from 17 and 25-item HAMD scales)* - Unscheduled Visit														
56	Physical Examination*														

AS NEEDED

* ***Please complete Physical Examination (End of Study) at the time of patient Termination, Withdrawal or Study Completion (CRF not in binder)***

PROTOCOL M/2020/0034

PART 2: SCHEDULE OF ACTIVITIES

(Check boxes as forms/activities are completed)

Study Activities \ Study Period	End of Week												End of Part 2 (FINAL)
	9	10	11	12	13	14	15	16	20	24	28	32	
DSM-IV 5-Axis Clinical Diagnosis												☐	
Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Vital Signs	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Study Medication Record	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Montgomery-Asberg Depression Rating Scale (MADRS)		☐		☐		☐		☐	☐	☐	☐	☐	
Clinical Global Impressions (CGI)		☐		☐		☐		☐	☐	☐	☐	☐	
Patient Global Impressions (PGI)		☐		☐		☐		☐	☐	☐	☐	☐	
SF-36 Health Survey		☐		☐		☐		☐	☐	☐	☐	☐	
Kellner Symptoms Questionnaire (KSQ)		☐		☐		☐		☐	☐	☐	☐	☐	
Social Adaptation Self-evaluation Scale (SASS)		☐		☐		☐		☐	☐	☐	☐	☐	
Rush Sexual Inventory Scale (RSI): Section B								☐				☐	
Electrocardiogram (ECG)												☐	
Pregnancy Test												☐	
MDD Relapse Based on 25-item HAMD Scale	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	
Study Termination Report - Part 2													☐
Adverse Event Form	**AS NEEDED**												
Concomitant Medication Form													
Serious Adverse Event Form													
Adverse Event Follow-up Report													
Exposure in Utero													
Serious Adverse Event Form - *Page 3 of 3 (Extra Form)*													
Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - Unscheduled Visit													
Addendum for Hamilton Psychiatric Rating Scale for Depression *(Includes additional symptoms from 17 and 25-item HAMD scales)*													
Physical Examination*													

* ***Please complete Physical Examination (End of Study) at the time of patient Termination, Withdrawal or Study Completion (CRF not in binder)***

PROTOCOL M/2020/0034

END OF WEEK 9

- Complete the following CRFs:

Page #	Form
1	Vital Signs / AE & Concomitant Medication / Study Medication Record
2-5	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
6	Addendum Hamilton Psychiatric Rating Scale for Depression
7	MDD Relapse Based on 25-item HAMD Scale

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 1)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 7.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 1)*. Review dosing instructions if indicated.

- Dispense Week 10's supply of study medication.

- Schedule patient for End of Week 10 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 9

All **End of Week 9** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	1	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	2	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	3	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	4	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	5	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	6	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	7	MDD Relapse Based on 25-item HAMD Scale

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 9

DataFax #147 Plate #021 Seq. #209

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 9

DataFax #147 Plate #015 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

Page 2

25-ITEM HAMD - *Page 1 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #016 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 9

DataFax #147 Plate #017 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

Page 4

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 9

DataFax #147 Plate #019 Seq. #209

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Page 6

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #209

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE: ***1. An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***

2. If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.

Investigator's Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 10

- Complete the following CRFs:

Page #	Form
8	Vital Signs / AE & Concomitant Medication / Study Medication Record
9-12	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
13	Addendum Hamilton Psychiatric Rating Scale for Depression
14	MDD Relapse Based on 25-item HAMD Scale
15-17	Montgomery - Asberg Depression Rating Scale (MADRS)
18	Clinical Global Impressions (CGI)
19	Patient Global Impressions (PGI)
20-22	SF-36 Health Survey
23-24	Kellner Symptom Questionnaire (KSQ)
25-26	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 8)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 14.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 8)*. Review dosing instructions if indicated.

- Dispense Week 11's supply of study medication.

- Schedule patient for End of Week 11 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 10

All **End of Week 10** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	8	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	9	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	10	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	11	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	12	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	13	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	14	MDD Relapse Based on 25-item HAMD Scale
☐	15	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	16	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	17	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	18	Clinical Global Impressions (CGI)
☐	19	Patient Global Impressions (PGI)
☐	20	SF-36 Health Survey - *Page 1 of 3*
☐	21	SF-36 Health Survey - *Page 2 of 3*
☐	22	SF-36 Health Survey - *Page 3 of 3*
☐	23	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	24	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	25	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	26	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 10

DataFax #147 Plate #021 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 10

DataFax #147 Plate #015 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

DataFax #147 Plate #016 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 10

DataFax #147 Plate #017 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

Page 11

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 10

DataFax #147 Plate #019 Seq. #210

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Page 13

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #210

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - *Page 1 of 3*

End of Week 10

DataFax #147 Plate #022 Seq. #210

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

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DataFax #147 Plate #023 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 10

DataFax #147 Plate #025 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

CLINICAL GLOBAL IMPRESSIONS (CGI)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PATIENT GLOBAL IMPRESSIONS (PGI)

End of Week 10

DataFax #147 Plate #026 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

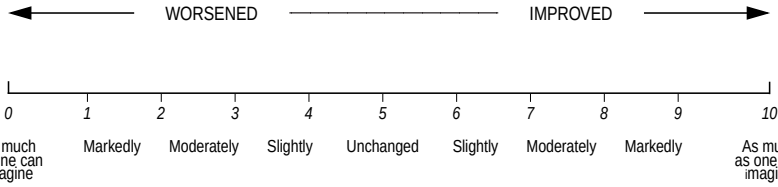
Randomization Number ☐☐☐☐

Principal Investigator _____ ☐☐☐☐☐

Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 10

DataFax #147 Plate #027 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ 1 *Excellent* ☐ 2 *Very Good* ☐ 3 *Good* ☐ 4 *Fair* ☐ 5 *Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ 1 *Much better now than one year ago*
☐ 2 *Somewhat better now than one year ago*
☐ 3 *About the same as one year ago*
☐ 4 *Somewhat worse now than one year ago*
☐ 5 *Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	1 Yes, Limited A Lot	2 Yes, Limited A Little	3 No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 10

DataFax #147 Plate #030 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 10

DataFax #147 Plate #031 Seq. #210

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐

	True	False
61. Not interested in things	☐	☐

	Yes	No
62. Highly strung	☐	☐

	True	False
63. Cannot relax	☐	☐

	Yes	No
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐

	True	False
78. No unpleasant feelings in head or body	☐	☐

	Yes	No
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 10

DataFax #147 Plate #032 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

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DataFax #147 Plate #033 Seq. #210

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 11

- Complete the following CRFs:

Page #	Form
27	Vital Signs / AE & Concomitant Medication / Study Medication Record
28-31	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
32	Addendum Hamilton Psychiatric Rating Scale for Depression
33	MDD Relapse Based on 25-item HAMD Scale

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 27).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 33.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 27).* Review dosing instructions if indicated.

- Dispense Week 12's supply of study medication.

- Schedule patient for End of Week 12 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #211

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 11

All **End of Week 11** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	27	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	28	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	29	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	30	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	31	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	32	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	33	MDD Relapse Based on 25-item HAMD Scale

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 11

DataFax #147 Plate #021 Seq. #211

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 11

DataFax #147 Plate #015 Seq. #211

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

DataFax #147 Plate #016 Seq. #211

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #211

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ *0 Absent*
- ☐ *1 Loss of appetite, mild or occasional*
- ☐ *2 Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ *0 Absent*
- ☐ *1 One or 2 pounds over the past month*
- ☐ *2 Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ *0 Absent*
- ☐ *1 Gained 1 or 2 pounds over the past month*
- ☐ *2 Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ *0 No loss of energy*
- ☐ *1 Subjective loss of energy or feelings of tiredness*
- ☐ *2 Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ *0 No loss of interest*
- ☐ *1 Mild loss of interest*
- ☐ *2 Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ *0 Absent*
- ☐ *1 Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ *2 Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ *3 Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ *4 Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ *0 No change*
- ☐ *1 Some loss of interest and performance*
- ☐ *2 Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ *0 Absent*
- ☐ *1 Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ *2 Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ *3 Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ *4 Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

DataFax #147 Plate #018 Seq. #211

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 11

DataFax #147 Plate #019 Seq. #211

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Page 32

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #211

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 12

- Complete the following CRFs:

Page #	Form
34	Vital Signs / AE & Concomitant Medication / Study Medication Record
35-38	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
39	Addendum Hamilton Psychiatric Rating Scale for Depression
40	MDD Relapse Based on 25-item HAMD Scale
41-43	Montgomery - Asberg Depression Rating Scale (MADRS)
44	Clinical Global Impressions (CGI)
45	Patient Global Impressions (PGI)
46-48	SF-36 Health Survey
49-50	Kellner Symptom Questionnaire (KSQ)
51-52	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 34).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 40.
  If patient has relapsed:

  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 34).* Review dosing instructions if indicated.

- Dispense Week 13's supply of study medication.

- Schedule patient for End of Week 13 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 12

All **End of Week 12** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	34	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	35	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	36	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	37	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	38	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	39	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	40	MDD Relapse Based on 25-item HAMD Scale
☐	41	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	42	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	43	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	44	Clinical Global Impressions (CGI)
☐	45	Patient Global Impressions (PGI)
☐	46	SF-36 Health Survey - *Page 1 of 3*
☐	47	SF-36 Health Survey - *Page 2 of 3*
☐	48	SF-36 Health Survey - *Page 3 of 3*
☐	49	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	50	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	51	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	52	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

DataFax #147 Plate #021 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 12

DataFax #147 Plate #015 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 12

DataFax #147 Plate #017 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 12

DataFax #147 Plate #019 Seq. #212

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #212

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE: ***1. An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***

2. If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 12

DataFax #147 Plate #022 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐

Principal Investigator _____ ☐☐☐☐☐

Country US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 12

DataFax #147 Plate #025 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

CLINICAL GLOBAL IMPRESSIONS (CGI)

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

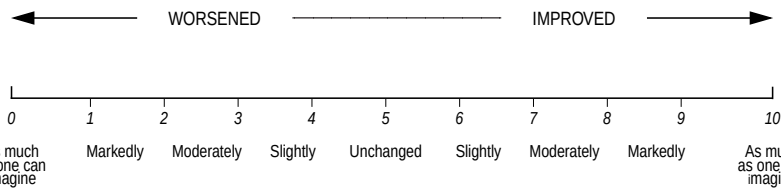
DataFax #147 Plate #026 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 12

DataFax #147 Plate #027 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 12

DataFax #147 Plate #030 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Page 49

DataFax #147 Plate #031 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐

	True	False
61. Not interested in things	☐	☐

	Yes	No
62. Highly strung	☐	☐

	True	False
63. Cannot relax	☐	☐

	Yes	No
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐

	True	False
78. No unpleasant feelings in head or body	☐	☐

	Yes	No
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 12

DataFax #147 Plate #032 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ *3 A lot of enjoyment?* ☐ *2 Some enjoyment?* ☐ *1 Only a little enjoyment?* ☐ *0 No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

5. Is the quality of your spare time:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ *3 Very frequently* ☐ *2 Frequently* ☐ *1 Rarely* ☐ *0 Never*

7. Is the state of relations in your family:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ *3 Many people?* ☐ *2 Some people?* ☐ *1 Only a few people?* ☐ *0 Nobody?*

9. Do you try to form relationships with others:
   ☐ *3 Very actively?* ☐ *2 Actively?* ☐ *1 Moderately actively?* ☐ *0 In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ *3 Very good* ☐ *2 Good* ☐ *1 Fair* ☐ *0 Unsatisfactory*

SASS - Page 1 of 2

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #033 Seq. #212

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 13

- Complete the following CRFs:

Page #	Form
53	Vital Signs / AE & Concomitant Medication / Study Medication Record
54-57	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
58	Addendum Hamilton Psychiatric Rating Scale for Depression
59	MDD Relapse Based on 25-item HAMD Scale

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 53).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 59.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 53).* Review dosing instructions if indicated.

- Dispense Week 14's supply of study medication.

- Schedule patient for End of Week 14 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 13

All **End of Week 13** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	53	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	54	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	55	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	56	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	57	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	58	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	59	MDD Relapse Based on 25-item HAMD Scale

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 13

DataFax #147 Plate #021 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 13

DataFax #147 Plate #015 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

DataFax #147 Plate #016 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 13

DataFax #147 Plate #017 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

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16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

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20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

DataFax #147 Plate #019 Seq. #213

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

DataFax #147 Plate #040 Seq. #213

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 14

- Complete the following CRFs:

Page #	Form
60	Vital Signs / AE & Concomitant Medication / Study Medication Record
61-64	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
65	Addendum Hamilton Psychiatric Rating Scale for Depression
66	MDD Relapse Based on 25-item HAMD Scale
67-69	Montgomery - Asberg Depression Rating Scale (MADRS)
70	Clinical Global Impressions (CGI)
71	Patient Global Impressions (PGI)
72-74	SF-36 Health Survey
75-76	Kellner Symptom Questionnaire (KSQ)
77-78	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 60).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 66.
  If patient has relapsed:

  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 60).* Review dosing instructions if indicated.

- Dispense Week 15's supply of study medication.

- Schedule patient for End of Week 15 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 14

All **End of Week 14** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	60	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	61	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	62	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	63	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	64	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	65	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	66	MDD Relapse Based on 25-item HAMD Scale
☐	67	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	68	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	69	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	70	Clinical Global Impressions (CGI)
☐	71	Patient Global Impressions (PGI)
☐	72	SF-36 Health Survey - *Page 1 of 3*
☐	73	SF-36 Health Survey - *Page 2 of 3*
☐	74	SF-36 Health Survey - *Page 3 of 3*
☐	75	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	76	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	77	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	78	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

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As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 14

DataFax #147 Plate #021 Seq. #214

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 14

DataFax #147 Plate #015 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

DataFax #147 Plate #017 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

DataFax #147 Plate #018 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 14

DataFax #147 Plate #019 Seq. #214

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 14

DataFax #147 Plate #022 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 14

DataFax #147 Plate #025 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

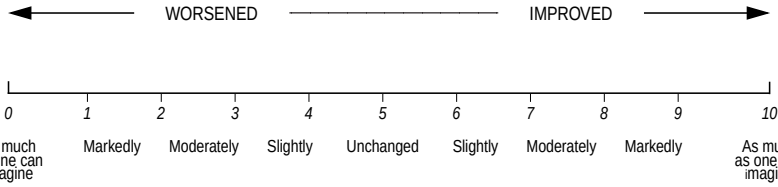
PATIENT GLOBAL IMPRESSIONS (PGI)

DataFax #147 Plate #026 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 14

DataFax #147 Plate #027 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 14

DataFax #147 Plate #030 Seq. #214

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 14

DataFax #147 Plate #031 Seq. #214

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐

	Yes	No
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 14

DataFax #147 Plate #032 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

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DataFax #147 Plate #033 Seq. #214

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 15

- Complete the following CRFs:

Page #	Form
79	Vital Signs / AE & Concomitant Medication / Study Medication Record
80-83	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
84	Addendum Hamilton Psychiatric Rating Scale for Depression
85	MDD Relapse Based on 25-item HAMD Scale

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 79).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 85.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 79).* Review dosing instructions if indicated.

- Dispense Week 16's supply of study medication.

- Schedule patient for End of Week 16 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 15

All **End of Week 15** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	79	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	80	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	81	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	82	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	83	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	84	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	85	MDD Relapse Based on 25-item HAMD Scale

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 15

DataFax #147 Plate #021 Seq. #215

Subject Number ☐☐-☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 15

DataFax #147 Plate #015 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

☐ 0 *Absent*
☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
☐ 4 *Extreme symptoms - complete withdrawal*
☐ *Can't rate*

2. Distinct quality of mood

☐ 0 *No distinct qualities*
☐ 1 *Mild or moderate (slightly different)*
☐ 2 *Severe (definitely different)*
☐ *Can't rate*

3. Lack of reactivity

☐ 0 *Reactive mood (mood varies according to situation)*
☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
☐ *Can't rate*

4. Diurnal variation

☐ 0 *No variation in mood*
☐ 1 *Mild variation between a.m. and p.m.*
☐ 2 *Definite variation between a.m. and p.m.*
☐ *Can't rate*

5. Worthlessness

☐ 0 *Not present*
☐ 1 *Mild feelings of low self-esteem evident only from questioning*
☐ 2 *Feelings of worthlessness*
☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
☐ *Can't rate*

6. Guilt

☐ 0 *Absent*
☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
☐ 4 *Delusional guilt, with hallucinations*
☐ *Can't rate*

DataFax #147 Plate #016 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 15

DataFax #147 Plate #017 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 15

DataFax #147 Plate #019 Seq. #215

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #215

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

PROTOCOL M/2020/0034

END OF WEEK 16

- Complete the following CRFs:

Page #	Form
86	Vital Signs / AE & Concomitant Medication / Study Medication Record
87-90	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
91	Addendum Hamilton Psychiatric Rating Scale for Depression
92	MDD Relapse Based on 25-item HAMD Scale
93-95	Montgomery - Asberg Depression Rating Scale (MADRS)
96	Clinical Global Impressions (CGI)
97	Patient Global Impressions (PGI)
98-100	SF-36 Health Survey
101-102	Kellner Symptom Questionnaire (KSQ)
103-104	Social Adaptation Self-Evaluation Scale (SASS)
105-107	Rush Sexual Inventory Scale (RSI): Section B

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 86).* Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 92.

  If patient has relapsed:

  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 86).* Review dosing instructions if indicated.

- Dispense Week 17-20's supply of study medication.

- Schedule patient for End of Week 20 visit *(Note: Change to monthly visit schedule).*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 16

All **End of Week 16** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	86	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	87	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	88	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	89	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	90	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	91	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	92	MDD Relapse Based on 25-item HAMD Scale
☐	93	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	94	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	95	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	96	Clinical Global Impressions (CGI)
☐	97	Patient Global Impressions (PGI)
☐	98	SF-36 Health Survey - *Page 1 of 3*
☐	99	SF-36 Health Survey - *Page 2 of 3*
☐	100	SF-36 Health Survey - *Page 3 of 3*
☐	101	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	102	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	103	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	104	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	105	Rush Sexual Inventory Scale (RSI): Section B - *Page 1 of 3*
☐	106	Rush Sexual Inventory Scale (RSI): Section B - *Page 2 of 3*
☐	107	Rush Sexual Inventory Scale (RSI): Section B - *Page 3 of 3*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

DataFax #147 Plate #021 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 16

DataFax #147 Plate #015 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 16

DataFax #147 Plate #017 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 16

DataFax #147 Plate #019 Seq. #216

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #216

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 16

DataFax #147 Plate #022 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 16

DataFax #147 Plate #025 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

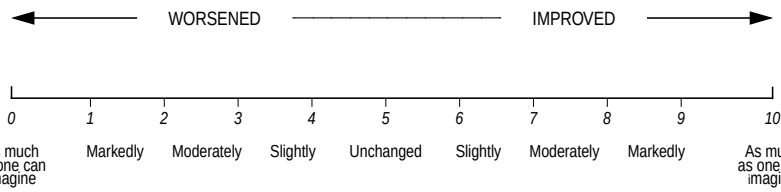
DataFax #147 Plate #026 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 16

DataFax #147 Plate #027 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

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DataFax #147 Plate #028 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 16

DataFax #147 Plate #030 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 16

DataFax #147 Plate #031 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐

	Yes	No
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 16

DataFax #147 Plate #032 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

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DataFax #147 Plate #033 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐

Principal Investigator _____ ☐☐☐☐☐

Country US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

DataFax #147 Plate #035 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

RSI

1. Rate each item as it applies in the PAST 4 WEEKS. For each item below, place a mark on the line where you would place yourself.

Example:

infrequent — *very frequent*

a. How frequently do you have pleasurable sexual thoughts?

infrequent — *very frequent*

b. Rate your ability to become sexually excited:

unable — *always able*

c. How frequently do you have desires to initiate sexual activity?

infrequent — *very frequent*

d. How often do you initiate sexual activity?

infrequent — *very frequent*

e. Rate your overall degree of sexual satisfaction attained:

low — *high*

2. How many times on average in the PAST 4 WEEKS did you engage in the following sexual activities?

Masturbation *(solitary or by partner)*:	**Intercourse *(anal or vaginal)*:**	**Oral sex:**
☐ *0 Never*	☐ *0 Never*	☐ *0 Never*
☐ *1 Once per week*	☐ *1 Once per week*	☐ *1 Once per week*
☐ *2 2-4 times per week*	☐ *2 2-4 times per week*	☐ *2 2-4 times per week*
☐ *3 5-10 times per week*	☐ *3 5-10 times per week*	☐ *3 5-10 times per week*
☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*

DataFax #147 Plate #036 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ *Site No.*

Subject's Initials ☐☐☐ *F M L*

Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐

Principal Investigator _____ ☐☐☐☐☐

Country US

RSI: Section B - Continued

MALES ONLY ☐ *N/A (female patient); If N/A is checked, go to question 3b.*

3a. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Spontaneous daytime erections	☐	☐
2. Painful erections	☐	☐
3. Erection when sexually aroused	☐	☐
4. Difficulty getting an erection when sexually stimulated	☐	☐
5. Difficulty maintaining an erection to complete sexual act	☐	☐
6. Waking up from sleep with an erection	☐	☐
7. Requiring more stimuli than usual to achieve an erection	☐	☐
8. Requiring more stimuli than usual to maintain an erection	☐	☐
9. Decreased fullness of erection	☐	☐
10. Increased sensitivity of genitals upon physical stimulation	☐	☐
11. Decreased sensitivity of genitals upon physical stimulation	☐	☐
12. Orgasm	☐	☐
13. Ejaculation	☐	☐
14. Painful orgasm/ejaculation	☐	☐
15. Orgasm without ejaculation	☐	☐
16. Delay in achieving orgasm/ejaculation but eventually doing so	☐	☐
17. Inability to achieve orgasm/ejaculation	☐	☐
18. Orgasm without erection	☐	☐
19. Orgasm occurring during sleep	☐	☐
20. Genital pain during sexual contact	☐	☐
21. Orgasm/ejaculation occurring earlier than desired	☐	☐
22. Experiencing orgasm without sexual provocation *(spontaneously, except in sleep)*	☐	☐
23. Generally decreased intensity of orgasm	☐	☐

Reviewer's Initials: _____

DataFax #147 Plate #037 Seq. #216

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

FEMALES ONLY ☐ *N/A (male patient)*

3b. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Increased sensitivity, other than pain, in breasts upon physical contact	☐	☐
2. Increased sensitivity of genitals, other than pain, upon physical contact	☐	☐
3. Pain in breasts upon physical contact	☐	☐
4. Pain in genitals upon physical contact	☐	☐
5. Decreased sensitivity in breasts upon physical contact	☐	☐
6. Decreased sensitivity in genitals upon physical contact	☐	☐
7. Inadequate swelling or vaginal lubrication during sexual arousal	☐	☐
8. Orgasm	☐	☐
9. Multiple orgasm	☐	☐
10. Difficulty achieving orgasm, but eventually being able to	☐	☐
11. Inability to achieve orgasm	☐	☐
12. Experiencing orgasm without sexual provocation *(spontaneously)*	☐	☐
13. Painful orgasm	☐	☐
14. Decreased intensity or orgasm	☐	☐
15. Involuntary vaginal contractions that prevent vaginal penetration	☐	☐
If Yes check one: ☐ *always* ☐ *intermittently*		
16. Physical pain during sexual activity	☐	☐

What was the first day of your last menstrual period: ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) ☐ *Not Applicable*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 20

- Complete the following CRFs:

Page #	Form
108	Vital Signs / AE & Concomitant Medication / Study Medication Record
109-112	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
113	Addendum Hamilton Psychiatric Rating Scale for Depression
114	MDD Relapse Based on 25-item HAMD Scale
115-117	Montgomery - Asberg Depression Rating Scale (MADRS)
118	Clinical Global Impressions (CGI)
119	Patient Global Impressions (PGI)
120-122	SF-36 Health Survey
123-124	Kellner Symptom Questionnaire (KSQ)
125-126	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 108)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 114.
  If patient has relapsed:
  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 108)*. Review dosing instructions if indicated.

- Dispense Week 21-24's supply of study medication.

- Schedule patient for End of Week 24 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 20

All **END OF WEEK 20** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	108	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	109	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	110	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	111	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	112	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	113	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	114	MDD Relapse Based on 25-item HAMD Scale
☐	115	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	116	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	117	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	118	Clinical Global Impressions (CGI)
☐	119	Patient Global Impressions (PGI)
☐	120	SF-36 Health Survey - *Page 1 of 3*
☐	121	SF-36 Health Survey - *Page 2 of 3*
☐	122	SF-36 Health Survey - *Page 3 of 3*
☐	123	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	124	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	125	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	126	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 20

DataFax #147 Plate #021 Seq. #220

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 20

DataFax #147 Plate #015 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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Page 109

DataFax #147 Plate #016 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 20

DataFax #147 Plate #017 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

End of Week 20

DataFax #147 Plate #018 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ *0 Absent*
- ☐ *1 Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ *2 Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ *3 Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ *4 Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ *0 Absent*
- ☐ *1 Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ *2 Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ *3 Strong conviction of presence of physical disease, querulous attitude*
- ☐ *4 Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ *0 Acknowledges being depressed or ill*
- ☐ *1 Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ *2 Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ *0 Absent*
- ☐ *1 Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ *2 Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ *3 Interview difficult, prolonged*
- ☐ *4 Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ *0 Absent*
- ☐ *1 Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ *2 High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 20

DataFax #147 Plate #019 Seq. #220

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Page 113

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #220

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE: ***1. An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***

2. If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 20

DataFax #147 Plate #022 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 20

DataFax #147 Plate #025 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

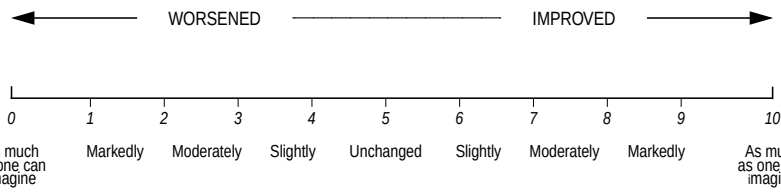
DataFax #147 Plate #026 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 20

DataFax #147 Plate #027 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 20

DataFax #147 Plate #030 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Page 123

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 20

DataFax #147 Plate #031 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Page 124

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 20

DataFax #147 Plate #032 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ *3 A lot of enjoyment?* ☐ *2 Some enjoyment?* ☐ *1 Only a little enjoyment?* ☐ *0 No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

5. Is the quality of your spare time:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ *3 Very frequently* ☐ *2 Frequently* ☐ *1 Rarely* ☐ *0 Never*

7. Is the state of relations in your family:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ *3 Many people?* ☐ *2 Some people?* ☐ *1 Only a few people?* ☐ *0 Nobody?*

9. Do you try to form relationships with others:
   ☐ *3 Very actively?* ☐ *2 Actively?* ☐ *1 Moderately actively?* ☐ *0 In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ *3 Very good* ☐ *2 Good* ☐ *1 Fair* ☐ *0 Unsatisfactory*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #033 Seq. #220

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ *3 Great value* ☐ *2 Some value* ☐ *1 Only a little value* ☐ *0 No value at all*

12. How often do people in your social circle seek contact with you?
☐ *3 Very often* ☐ *2 Often* ☐ *1 Rarely* ☐ *0 Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ *3 Always* ☐ *2 Most of the time* ☐ *1 Rarely* ☐ *0 Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ *3 Fully* ☐ *2 Moderately* ☐ *1 Slightly* ☐ *0 Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ *3 Very much* ☐ *2 Moderately* ☐ *1 Not much* ☐ *0 Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Only slightly* ☐ *0 Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

18. How often do you feel rejected, excluded from your circle?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

19. How important do you consider your physical appearance?
☐ *3 Very* ☐ *2 Moderately* ☐ *1 Not very much* ☐ *0 Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ *0 Always* ☐ *1 Often* ☐ *2 Sometimes* ☐ *3 Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ *3 Very much so* ☐ *2 Moderately* ☐ *1 Not very* ☐ *0 Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 24

- Complete the following CRFs:

Page #	Form
127	Vital Signs / AE & Concomitant Medication / Study Medication Record
128-131	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
132	Addendum Hamilton Psychiatric Rating Scale for Depression
133	MDD Relapse Based on 25-item HAMD Scale
134-136	Montgomery - Asberg Depression Rating Scale (MADRS)
137	Clinical Global Impressions (CGI)
138	Patient Global Impressions (PGI)
139-141	SF-36 Health Survey
142-143	Kellner Symptom Questionnaire (KSQ)
144-145	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 127)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 133.
  If patient has relapsed:

  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 127)*. Review dosing instructions if indicated.

- Dispense Week 25-28's supply of study medication.

- Schedule patient for End of Week 28 visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 24

All **END OF WEEK 24** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	127	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	128	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	129	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	130	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	131	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	132	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	133	MDD Relapse Based on 25-item HAMD Scale
☐	134	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	135	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	136	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	137	Clinical Global Impressions (CGI)
☐	138	Patient Global Impressions (PGI)
☐	139	SF-36 Health Survey - *Page 1 of 3*
☐	140	SF-36 Health Survey - *Page 2 of 3*
☐	141	SF-36 Health Survey - *Page 3 of 3*
☐	142	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	143	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	144	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	145	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 24

DataFax #147 Plate #021 Seq. #224

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs* Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,* Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐ Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 24

DataFax #147 Plate #015 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 24

DataFax #147 Plate #017 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 4 of 4***

End of Week 24

DataFax #147 Plate #018 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

25-ITEM HAMD - *Page 4 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 24

DataFax #147 Plate #019 Seq. #224

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

Page 132

ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 24

DataFax #147 Plate #022 Seq. #224

Subject Number ___ - ____ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ____ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

- ☐ 0 *No sadness.*
- ☐ 1
- ☐ 2 *Looks dispirited but does brighten up without difficulty.*
- ☐ 3
- ☐ 4 *Appears sad and unhappy most of the time.*
- ☐ 5
- ☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

- ☐ 0 *Occasional sadness in keeping with the circumstances.*
- ☐ 1
- ☐ 2 *Sad or low but brightens up without difficulty.*
- ☐ 3
- ☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
- ☐ 5
- ☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

- ☐ 0 *Placid. Only fleeting inner tension.*
- ☐ 1
- ☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
- ☐ 3
- ☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
- ☐ 5
- ☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 24

DataFax #147 Plate #025 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

CLINICAL GLOBAL IMPRESSIONS (CGI)

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

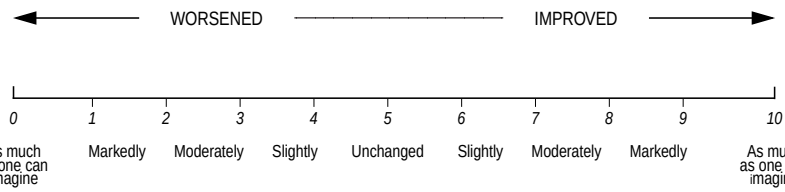
DataFax #147 Plate #026 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 24

DataFax #147 Plate #027 Seq. #224

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

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DataFax #147 Plate #028 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 24

DataFax #147 Plate #030 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 24

DataFax #147 Plate #031 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐

	True	False
61. Not interested in things	☐	☐

	Yes	No
62. Highly strung	☐	☐

	True	False
63. Cannot relax	☐	☐

	Yes	No
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐

	True	False
78. No unpleasant feelings in head or body	☐	☐

	Yes	No
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 24

DataFax #147 Plate #032 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ *3 A lot of enjoyment?* ☐ *2 Some enjoyment?* ☐ *1 Only a little enjoyment?* ☐ *0 No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

5. Is the quality of your spare time:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ *3 Very frequently* ☐ *2 Frequently* ☐ *1 Rarely* ☐ *0 Never*

7. Is the state of relations in your family:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ *3 Many people?* ☐ *2 Some people?* ☐ *1 Only a few people?* ☐ *0 Nobody?*

9. Do you try to form relationships with others:
   ☐ *3 Very actively?* ☐ *2 Actively?* ☐ *1 Moderately actively?* ☐ *0 In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ *3 Very good* ☐ *2 Good* ☐ *1 Fair* ☐ *0 Unsatisfactory*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #033 Seq. #224

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 28

- Complete the following CRFs:

Page #	Form
146	Vital Signs / AE & Concomitant Medication / Study Medication Record
147-150	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
151	Addendum Hamilton Psychiatric Rating Scale for Depression
152	MDD Relapse Based on 25-item HAMD Scale
153-155	Montgomery - Asberg Depression Rating Scale (MADRS)
156	Clinical Global Impressions (CGI)
157	Patient Global Impressions (PGI)
158-160	SF-36 Health Survey
161-162	Kellner Symptom Questionnaire (KSQ)
163-164	Social Adaptation Self-Evaluation Scale (SASS)

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 146)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form

- Assess patient regarding MDD relapse and record on CRF page 152.
  If patient has relapsed:

  a. Patient should be discontinued from the study.
  b. Complete all tests and forms contained in the End of Week 32 visit section.
  c. 12-Lead ECG *(Note: Mail duplicate original ECG to Premier)*
  d. Safety Laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*
  e. Collect Part 2 Dosing Diary and remaining Study Medication and bottles.
  f. Also complete the Study Termination Report - Part 2 on page 189.

- Check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 146)*. Review dosing instructions if indicated.

- Dispense Week 29-32's supply of study medication.

- Schedule patient for End of Week 32/FINAL visit.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 28

All **END OF WEEK 28** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	146	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	147	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	148	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	149	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	150	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	151	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	152	MDD Relapse Based on 25-item HAMD Scale
☐	153	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	154	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	155	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	156	Clinical Global Impressions (CGI)
☐	157	Patient Global Impressions (PGI)
☐	158	SF-36 Health Survey - *Page 1 of 3*
☐	159	SF-36 Health Survey - *Page 2 of 3*
☐	160	SF-36 Health Survey - *Page 3 of 3*
☐	161	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	162	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	163	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	164	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*

As Needed Form

☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 28

DataFax #147 Plate #021 Seq. #228

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 28

DataFax #147 Plate #015 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

- ☐ 0 *Absent*
- ☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
- ☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
- ☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
- ☐ 4 *Extreme symptoms - complete withdrawal*
- ☐ *Can't rate*

2. Distinct quality of mood

- ☐ 0 *No distinct qualities*
- ☐ 1 *Mild or moderate (slightly different)*
- ☐ 2 *Severe (definitely different)*
- ☐ *Can't rate*

3. Lack of reactivity

- ☐ 0 *Reactive mood (mood varies according to situation)*
- ☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
- ☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
- ☐ *Can't rate*

4. Diurnal variation

- ☐ 0 *No variation in mood*
- ☐ 1 *Mild variation between a.m. and p.m.*
- ☐ 2 *Definite variation between a.m. and p.m.*
- ☐ *Can't rate*

5. Worthlessness

- ☐ 0 *Not present*
- ☐ 1 *Mild feelings of low self-esteem evident only from questioning*
- ☐ 2 *Feelings of worthlessness*
- ☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
- ☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
- ☐ *Can't rate*

6. Guilt

- ☐ 0 *Absent*
- ☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
- ☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
- ☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
- ☐ 4 *Delusional guilt, with hallucinations*
- ☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 28

DataFax #147 Plate #017 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

---

16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

---

20. Psychic anxiety - *anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 28

DataFax #147 Plate #019 Seq. #228

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

NOTE:
1. ***An optional, additional subject visit is allowed within 10 days to re-check the HAMD score once a subject reaches 50%. Complete on "Unscheduled" HAMD case report form (in back of CRF binder) for the optional, additional visit.***
2. ***If Yes, subject should be discontinued from the study. Also complete all case report forms for this visit and the Study Termination Report on page 189.***

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 28

DataFax #147 Plate #022 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

---

6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

---

10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 28

DataFax #147 Plate #025 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

Initials or Signature: _____

PATIENT GLOBAL IMPRESSIONS (PGI)

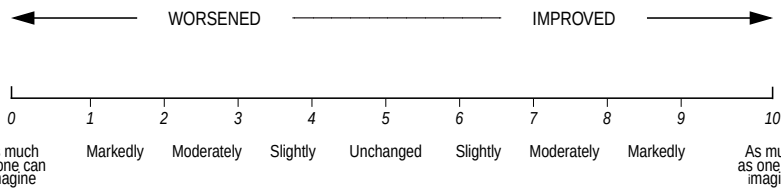
DataFax #147 Plate #026 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 28

DataFax #147 Plate #027 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ *1 Excellent* ☐ *2 Very Good* ☐ *3 Good* ☐ *4 Fair* ☐ *5 Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ *1 Much better now than one year ago*
☐ *2 Somewhat better now than one year ago*
☐ *3 About the same as one year ago*
☐ *4 Somewhat worse now than one year ago*
☐ *5 Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	*1* **Yes, Limited A Lot**	*2* **Yes, Limited A Little**	*3* **No, Not Limited At All**
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Were limited in the kind of work or other activities	☐	☐
d. Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

	1 Yes	2 No
a. Cut down on the amount of time you spent on work or other activities	☐	☐
b. Accomplished less than you would like	☐	☐
c. Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 28

DataFax #147 Plate #030 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Page 161

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 28

DataFax #147 Plate #031 Seq. #228

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐
	True	**False**
61. Not interested in things	☐	☐
	Yes	**No**
62. Highly strung	☐	☐
	True	**False**
63. Cannot relax	☐	☐
	Yes	**No**
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐

	Yes	No
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐
	True	**False**
78. No unpleasant feelings in head or body	☐	☐
	Yes	**No**
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 28

DataFax #147 Plate #032 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ *3 A lot of enjoyment?* ☐ *2 Some enjoyment?* ☐ *1 Only a little enjoyment?* ☐ *0 No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ *3 Very* ☐ *2 Moderately* ☐ *1 A little* ☐ *0 Not at all*

5. Is the quality of your spare time:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ *3 Very frequently* ☐ *2 Frequently* ☐ *1 Rarely* ☐ *0 Never*

7. Is the state of relations in your family:
   ☐ *3 Very good?* ☐ *2 Good?* ☐ *1 Fair?* ☐ *0 Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ *3 Many people?* ☐ *2 Some people?* ☐ *1 Only a few people?* ☐ *0 Nobody?*

9. Do you try to form relationships with others:
   ☐ *3 Very actively?* ☐ *2 Actively?* ☐ *1 Moderately actively?* ☐ *0 In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ *3 Very good* ☐ *2 Good* ☐ *1 Fair* ☐ *0 Unsatisfactory*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #033 Seq. #228

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

PROTOCOL M/2020/0034

END OF WEEK 32 / FINAL VISIT

- Complete the following CRFs:

Page #	Form
165	Vital Signs / AE & Concomitant Medication / Study Medication Record
166	Electrocardiogram (ECG) / Pregnancy Test *(Note: Mail duplicate original ECG to Premier)*
167-170	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)
171	Addendum Hamilton Psychiatric Rating Scale for Depression
172	MDD Relapse Based on 25-item HAMD Scale
173-175	Montgomery - Asberg Depression Rating Scale (MADRS)
176	Clinical Global Impressions (CGI)
177	Patient Global Impressions (PGI)
178-180	SF-36 Health Survey
181-182	Kellner Symptom Questionnaire (KSQ)
183-184	Social Adaptation Self-Evaluation Scale (SASS)
185-187	Rush Sexual Inventory Scale (RSI): Section B
188	DSM-IV 5-Axis Clinical Diagnosis
PE	Physical Examination - End of Study *(CRF not in binder)*
189	Study Termination Report - Part 2

- Draw safety laboratory *(Chemistry panel, CBC, UA, UDS, Pregnancy Test)*

- Question patient regarding Adverse Events and Concomitant Medications *(CRF page 165)*. Complete the following if indicated.

AEF	Adverse Event Form
CM	Concomitant Medication Form
AEFUP	Adverse Event Follow-up Report *(if additional follow-up indicated) - Follow up all open Adverse Event(s) until they resolve (see Protocol page 34)*

- Collect and check patient's Part 2 Dosing Diary and Study Medication Compliance *(Record on CRF page 165).*

- Collect any remaining study medication or containers from patient.

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

TRANSMITTAL FORM - PART 2

DataFax #147 Plate #500 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

END OF WEEK 32 / FINAL VISIT

All **End of Week 32** case report forms should be faxed to the DataFax system (1-888-272-7778).

Check box if faxed	Page #	Form
☐	165	Vital Signs / AE & Concomitant Medication / Study Medication Record
☐	166	Electrocardiogram (ECG) / Pregnancy Test
☐	167	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 1 of 4*
☐	168	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 2 of 4*
☐	169	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 3 of 4*
☐	170	Hamilton Psychiatric Rating Scale for Depression (25-item HAMD) - *Page 4 of 4*
☐	171	Addendum Hamilton Psychiatric Rating Scale for Depression
☐	172	MDD Relapse Based on 25-item HAMD Scale
☐	173	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 1 of 3*
☐	174	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 2 of 3*
☐	175	Montgomery - Asberg Depression Rating Scale (MADRS) - *Page 3 of 3*
☐	176	Clinical Global Impressions (CGI)
☐	177	Patient Global Impressions (PGI)
☐	178	SF-36 Health Survey - *Page 1 of 3*
☐	179	SF-36 Health Survey - *Page 2 of 3*
☐	180	SF-36 Health Survey - *Page 3 of 3*
☐	181	Kellner Symptom Questionnaire (KSQ) - *Page 1 of 2*
☐	182	Kellner Symptom Questionnaire (KSQ) - *Page 2 of 2*
☐	183	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	184	Social Adaptation Self-Evaluation Scale (SASS) - *Page 1 of 2*
☐	185	Rush Sexual Inventory Scale (RSI): Section B - *Page 1 of 3*
☐	186	Rush Sexual Inventory Scale (RSI): Section B - *Page 2 of 3*
☐	187	Rush Sexual Inventory Scale (RSI): Section B - *Page 3 of 3*
☐	188	DSM-IV 5-Axis Clinical Diagnosis
☐	PE	Physical Examination - End of Study *(CRF not in binder)*
☐	189	Study Termination Report - Part 2
As Needed Form		
☐	AEF	Adverse Event Form
☐	CM	Concomitant Medication Form
☐	AEFUP	Adverse Event Follow-up Report

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

VITAL SIGNS / AE & CONCOMITANT MEDICATION / STUDY MEDICATION RECORD

End of Week 32

DataFax #147 Plate #021 Seq. #232

Subject Number ☐☐-☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

VS / AE & CONCOMITANT MED. / STUDY MED. RECORD

VITAL SIGNS

Weight *(without shoes):* ☐☐☐ *lbs*

Sitting Blood Pressure: ☐☐☐ / ☐☐☐ *mmHg* (*Systolic* / *Diastolic*)

Sitting Pulse: ☐☐☐ */min,*

Respiration Rate: ☐☐ */min*

Temperature: ☐☐☐.☐ °*F*

Were any clinically significant changes in vital signs observed at this examination?

☐ *No* ☐ *Yes, specify*:* _____

**** If any changes are considered to be an Adverse Event, also complete an ADVERSE EVENT FORM (AEF).***

ADVERSE EVENTS AND CONCOMITANT MEDICATION

If there is any change in reported adverse event(s) from previous visits, please update ADVERSE EVENT FORM (AEF).

Has the subject had any **new** adverse events since the last visit?

☐ *No* ☐ *Yes* If *Yes*, record the event(s) on the ADVERSE EVENT forms.

Have there been any changes in concomitant medication since the last visit?

☐ *No* ☐ *Yes* If *Yes,* update the CONCOMITANT MEDICATION forms.

STUDY MEDICATION RECORD

Total number of tablets returned today: ☐☐.☐

Total number of tablets dispensed today: ☐☐

Did the subject skip drug for more than 2 doses per week?

☐ *No* ☐ *Yes* *Comments, if any:* _____

Since the last visit, what has been the patient's usual total daily dose?

☐ *2 tabs* ☐ *2 1/2 tabs* ☐ *Other, specify:* _____

Initials or Signature: _____

DataFax #147 Plate #038 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

ELECTROCARDIOGRAM *(ECG)*

Date ECG Performed ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) Time ☐☐:☐☐ *hours* (*00:01 - 24:00*)

Date of last dose of study medication ☐☐☐☐☐☐☐☐ (*y y y y m m d d*) Time ☐☐:☐☐ *hours* (*00:01 - 24:00*)

Are there any clinically significant changes noted from Screen ECG? ☐ *No* ☐ *Yes*

Note: Please mail a duplicate original Electrocardiogram (ECG) to PREMIER.

PREGNANCY TEST *(Serum)*

NOT DONE, Reason: ☐ *Male* ☐ *Surgically sterile* ☐ *Postmenopausal (>2 years)*

DONE, Result: ☐ *Negative* ☐ *Positive* ☐ *Inconclusive*

Note: If test is positive or inconclusive, subject should be removed from the study.

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 1 of 4***

End of Week 32

DataFax #147 Plate #015 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD

INSTRUCTIONS: The time frame for this scale is the past week, except where otherwise indicated on specific items.

25-ITEM HAMD - *Page 1 of 4*

1. Depressed mood

☐ 0 *Absent*
☐ 1 *Mild - gloomy attitude, may be accompanied by infrequent weeping spells, sad, blue, waning of interests*
☐ 2 *Moderate - may be accompanied by feelings of inadequacy, self-pity, worrying, decrease in social interests and activity level, pessimism, "Locked in", occasional weeping, apathy, decrease in experience of pleasure*
☐ 3 *Severe - may be characterized by hopelessness, greater tendency to withdraw socially, near absence of interest or participation in other than essential activities, hardly anything produces pleasure, weeping may be frequent (or beyond tears)*
☐ 4 *Extreme symptoms - complete withdrawal*
☐ *Can't rate*

2. Distinct quality of mood

☐ 0 *No distinct qualities*
☐ 1 *Mild or moderate (slightly different)*
☐ 2 *Severe (definitely different)*
☐ *Can't rate*

3. Lack of reactivity

☐ 0 *Reactive mood (mood varies according to situation)*
☐ 1 *Mild to moderate lack of reactivity (patient's mood is somewhat reactive but also has a constant depressive overtone)*
☐ 2 *Severe lack of reactivity (patient's mood lacks any reactivity to situational factors)*
☐ *Can't rate*

4. Diurnal variation

☐ 0 *No variation in mood*
☐ 1 *Mild variation between a.m. and p.m.*
☐ 2 *Definite variation between a.m. and p.m.*
☐ *Can't rate*

5. Worthlessness

☐ 0 *Not present*
☐ 1 *Mild feelings of low self-esteem evident only from questioning*
☐ 2 *Feelings of worthlessness*
☐ 3 *Strong feelings of worthlessness - differs from "2" by degree ("I am no good ar all." "Inferior to all others.")*
☐ 4 *Delusions of worthlessness ("I am a heap of garbage." "I am a sinner." etc.)*
☐ *Can't rate*

6. Guilt

☐ 0 *Absent*
☐ 1 *Feelings of self-reproach, self-blame, specific instance of lapse*
☐ 2 *Thoughts that negative events or reactions were caused by oneself; general or many instances or lapses for which one feels guilty; stronger convictions of one's guilt*
☐ 3 *Belief that illness might be a punishment, possibly delusional guilt*
☐ 4 *Delusional guilt, with hallucinations*
☐ *Can't rate*

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DataFax #147 Plate #016 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

7. Helplessness

- ☐ 0 *Not present*
- ☐ 1 *Patient reports mild feelings of helplessness upon questioning ("There are some things that I can't change.")*
- ☐ 2 *Moderate feelings of helplessness ("I can't seem to change most things in my life.")*
- ☐ 3 *Strong feelings of helplessness ("I can't change anything in my life.")*
- ☐ 4 *Strong feelings of helplessness and has given up routine activities of normal life (decreased personal hygiene, doesn't get out of bed, difficulty feeding self, etc.)*
- ☐ *Can't rate*

8. Hopelessness

- ☐ 0 *Not present*
- ☐ 1 *Intermittently doubts that things will improve but can be reassured*
- ☐ 2 *Consistently feels hopeless but accepts reassurances*
- ☐ 3 *Expresses feelings of discouragement, despair, pessimism about the future, which cannot be dispelled*
- ☐ 4 *Spontaneously and inappropriately perseverates, "I'll never get well" or equivalent*
- ☐ *Can't rate*

9. Suicide

- ☐ 0 *Absent*
- ☐ 1 *Feels life is not worth living*
- ☐ 2 *Wishes he were dead or any thoughts of possible death to himself*
- ☐ 3 *Suicidal ideas, gestures, or plans*
- ☐ 4 *Attempted suicide (any serious attempt rated 4)*
- ☐ *Can't rate*

Insomnia

10. Early

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild, trivial (less than 1-hour delay)*
- ☐ 2 *Frequent (3 or more times per week) and severe (1 hour or more delay)*
- ☐ *Can't rate*

11. Middle

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1-hour delay in returning to sleep)*
- ☐ 2 *Frequent (several times per night with difficulty returning to sleep, 3 or more times per week) and severe (1 hour or more to return to sleep)*
- ☐ *Can't rate*

12. Late

- ☐ 0 *Absent*
- ☐ 1 *Occasional (fewer than 3 days a week), mild (less than 1 hour early)*
- ☐ 2 *Frequent (3 or more days per week) and severe (1 hour or more early)*
- ☐ *Can't rate*

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (25-ITEM HAMD) - ***Page 3 of 4***

End of Week 32

DataFax #147 Plate #017 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

13. Loss of appetite

- ☐ 0 *Absent*
- ☐ 1 *Loss of appetite, mild or occasional*
- ☐ 2 *Loss of appetite, severe or constant: constipation*
- ☐ *Can't rate*

14. Loss of weight

- ☐ 0 *Absent*
- ☐ 1 *One or 2 pounds over the past month*
- ☐ 2 *Three pounds or more over the past month*
- ☐ *Can't rate*

15. Weight gain

- ☐ 0 *Absent*
- ☐ 1 *Gained 1 or 2 pounds over the past month*
- ☐ 2 *Gained 3 or more pounds over the last month*
- ☐ *Can't rate*

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16. Loss of energy

- ☐ 0 *No loss of energy*
- ☐ 1 *Subjective loss of energy or feelings of tiredness*
- ☐ 2 *Marked interferences with functioning (decrease in work and activities), feelings of heaviness or achiness*
- ☐ *Can't rate*

17. Loss of interest

- ☐ 0 *No loss of interest*
- ☐ 1 *Mild loss of interest*
- ☐ 2 *Severe loss of interest in most activities, including clothes, food, and appearance*
- ☐ *Can't rate*

18. Work and activities

- ☐ 0 *Absent*
- ☐ 1 *Somewhat decreased efficiency, effortfulness; and/or decreased interest in or gets less pleasure from hobbies, interest, social contacts*
- ☐ 2 *Decreased performance, neglects or delays some things; withdraws from unnecessary activity, decreased participation in hobbies, social events*
- ☐ 3 *Considerably diminished performances of work or routine activities, more things are neglected or postponed indefinitely, virtually unproductive; avoids social contacts, nothing seems pleasurable, no interests*
- ☐ 4 *Unable to work, nonproductive, completely immobilized*
- ☐ *Can't rate*

19. Loss of libido

- ☐ 0 *No change*
- ☐ 1 *Some loss of interest and performance*
- ☐ 2 *Almost total loss of interest and sexual activity*
- ☐ *Can't rate*

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20. Psychic anxiety *- anxious, tense, jittery, nervous, restless, "up tight," apprehensive, frightened, scared, irritable, worrying*

- ☐ 0 *Absent*
- ☐ 1 *Transient tension, occasional irritability, mild exaggeration of worrying*
- ☐ 2 *Fairly constant tension, more frequent irritability, somewhat "hyper" or jittery.*
- ☐ 3 *Pervasive apprehension, tension, irritability, constant ruminative worrying*
- ☐ 4 *Panic attacks: phobias restrict activity*
- ☐ *Can't rate*

25-ITEM HAMD - *Page 3 of 4*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #018 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

25 ITEM HAMD - Continued

21. Somatic anxiety - (***Note:*** *Symptoms are rated on the basis of the report of symptoms in the following systems (a) respiratory: labored breathing, shortness of breath, smothering or choking feelings, etc.; (b) cardiovascular: flushing, accelerated heart rate, palpitations, faintness, chest pain or discomfort, etc.; (c) gastrointestinal: indigestion, stomach upset, heartburn, stomach cramps, diarrhea, etc.; (d) genito-urinary frequency; (e) sweating; (f) giddiness, blurred vision, tinnitus; (g) neuromuscular, trembling or shaking, headaches, muscle tension, dizziness, tingling, etc.)*

- ☐ 0 *Absent*
- ☐ 1 *Mild - one or more symptoms, complains of some discomfort but continues to participate in daily activities*
- ☐ 2 *Moderate - e.g., symptoms from more than one system, occasionally patient can't take part in activities because of bodily discomfort*
- ☐ 3 *Severe - symptoms so uncomfortable that patient frequently has trouble taking part in activities*
- ☐ 4 *Extreme - multiple systems that are incapacitating, i.e., bodily discomfort precludes taking part in any activities*
- ☐ *Can't rate*

22. Hypochondriasis

- ☐ 0 *Absent*
- ☐ 1 *Preoccupation with health, bodily function, trivial or doubtful symptoms*
- ☐ 2 *Much preoccupation with physical symptoms, thoughts of organic disease*
- ☐ 3 *Strong conviction of presence of physical disease, querulous attitude*
- ☐ 4 *Hypochondriacal delusions and hallucinations, e.g., rotting, blockages, etc.*
- ☐ *Can't rate*

23. Insight

- ☐ 0 *Acknowledges being depressed or ill*
- ☐ 1 *Acknowledges illness but attributes cause to unlikely factors, e.g., bad food, climate, overwork, etc.*
- ☐ 2 *Denies being ill*
- ☐ *Can't rate*

24. Retardation

- ☐ 0 *Absent*
- ☐ 1 *Slight retardation at interview; flattening of affect and fixity of expression*
- ☐ 2 *Obvious retardation at interview; monotonous voice; delay in answering, motionless*
- ☐ 3 *Interview difficult, prolonged*
- ☐ 4 *Complete stupor*
- ☐ *Can't rate*

25. Agitation

- ☐ 0 *Absent*
- ☐ 1 *Low level of agitation, fidgeting, obvious restlessness (e.g., picking at hands or clothing, leg movements) for large proportion of interview*
- ☐ 2 *High level of agitation, includes fidgeting, obvious restlessness as well as the patient getting up during the interview, pacing, etc.*
- ☐ *Can't rate*

TOTAL SCORE: ☐☐☐

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

ADDENDUM FOR HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION ***(Includes additional symptoms from 17 and 28-item HAMD Scales)***

End of Week 32

DataFax #147 Plate #019 Seq. #232

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

26. Somatic Symptoms-Gastrointestinal

- ☐ 0 *None*
- ☐ 1 *Loss of appetite but eating without staff encouragement. Heavy feeling in abdomen*
- ☐ 2 *Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for GI symptoms*

27. Somatic Symptoms-General

- ☐ 0 *None*
- ☐ 1 *Heaviness in limbs, back, or head. Backache, headache, muscle ache. Loss of energy and fatigability*
- ☐ 2 *Any clear-cut symptom rates 2*

28. Depersonalization and Derealization *(such as: feelings of unreality, nihilistic ideas)*

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Moderate*
- ☐ 3 *Severe*
- ☐ 4 *Incapacitating*

29. Paranoid Symptoms

- ☐ 0 *None*
- ☐ 1 *Mildly suspicious*
- ☐ 2 *Moderately suspicious*
- ☐ 3 *Ideas of reference*
- ☐ 4 *Delusions of reference and persecution*

30. Obsessional and Compulsive Symptoms

- ☐ 0 *Absent*
- ☐ 1 *Mild*
- ☐ 2 *Severe*

31. Hypersomnia-Early bedtime

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than 60 minutes*
- ☐ 2 *Obvious/definite more than 60 minutes earlier most nights*

32. Hypersomnia-Oversleeping *(sleeping more than usual)*:

- ☐ 0 *No*
- ☐ 1 *Mild, infrequent-less than an hour*
- ☐ 2 *Obvious/definite-oversleeps more than an hour most days*

33. Hypersomnia-Napping

- ☐ 0 *Absent*
- ☐ 1 *Mild, infrequent-naps less than 30 minutes, or reports excessive daytime sleepiness*
- ☐ 2 *Obvious/definite-naps more than 30 minutes most days*

34. Increased Appetite *(change in appetite marked by increased food intake, or excessive cravings)*:

- ☐ 0 *Absent*
- ☐ 1 *Minimal-light increase in appetite; food cravings*
- ☐ 2 *Definite-marked increase in food intake or cravings*

35. Psychic Retardation *(slowness of speech and thought process: describes inhibition of will or feeling as if thought processes are paralyzed. Rate on basis of both observations and self-report but separate from usual motoric retardation)*:

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight slowing of speech, thought process*
- ☐ 2 *Moderate-delay in answering questions, describes volitional inhibition*
- ☐ 3 *Severe; slowness of speech and thought process sufficient to markedly prolong the interview*
- ☐ 4 *Extreme; nearly mute, minimally responsive*

36. Motoric Retardation

- ☐ 0 *Absent*
- ☐ 1 *Mild; slight flattening of affect, fixity of expression*
- ☐ 2 *Moderate-monotonous voice and decrease in spontaneous movements*
- ☐ 3 *Severe-obvious slowness of movement, gait; blunted affect*
- ☐ 4 *Extreme-stuporous; marked motoric retardation observed in gait and posture*

Initials or Signature: _____

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ADDENDUM FOR HAMD

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #040 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐☐☐☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

Did subject have a relapse?..... ☐ *No* ☐ *Yes*

("Yes", defined as a 50% or greater increase of 25-item HAMD total score compared to the Day 57 HAMD total score, and a minimum HAMD total score of ≥ 10)

Investigator's Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

MONTGOMERY-ASBERG DEPRESSION RATING SCALE (MADRS) - ***Page 1 of 3***

End of Week 32

DataFax #147 Plate #022 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS

INSTRUCTIONS: For each symptom, place a check mark in the box next to the response which best describes this patient's status during the past week. The rating may lie on a defined scale step (0, 2, 4, 6) or between steps (1, 3, 5).

MADRS - *Page 1 of 3*

1. Apparent Sadness

Representing despondency, gloom and despair, *(more than just ordinary transient low spirits)* reflected in speech, facial expression, and posture. Rate by depth and inability to brighten up.

☐ 0 *No sadness.*
☐ 1
☐ 2 *Looks dispirited but does brighten up without difficulty.*
☐ 3
☐ 4 *Appears sad and unhappy most of the time.*
☐ 5
☐ 6 *Looks miserable all the time. Extremely despondent.*

---

2. Reported Sadness

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope. Rate according to intensity, duration, and the extent to which the mood is reported to be influenced by events.

☐ 0 *Occasional sadness in keeping with the circumstances.*
☐ 1
☐ 2 *Sad or low but brightens up without difficulty.*
☐ 3
☐ 4 *Pervasive feelings of sadness or gloominess. The mood is still influenced by external circumstances.*
☐ 5
☐ 6 *Continuous or unvarying sadness, misery or despondency.*

---

3. Inner Tension

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread, or anguish. Rate according to intensity, frequency, duration, and the extent of reassurance called for.

☐ 0 *Placid. Only fleeting inner tension.*
☐ 1
☐ 2 *Occasional feelings of edginess and ill-defined discomfort.*
☐ 3
☐ 4 *Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.*
☐ 5
☐ 6 *Unrelenting dread or anguish. Overwhelming panic.*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #023 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

4. Reduced Sleep

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

- ☐ 0 *Sleeps as usual.*
- ☐ 1
- ☐ 2 *Slight difficulty dropping off to sleep or slightly reduced, light, or fitful sleep.*
- ☐ 3
- ☐ 4 *Sleep reduced or broken by at least 2 hours.*
- ☐ 5
- ☐ 6 *Less than 2 or 3 hours sleep.*

---

5. Reduced Appetite

Representing the feeling of a loss of appetite compared with when well. Rate by loss of desire for food or the need to force oneself to eat.

- ☐ 0 *Normal or increased appetite.*
- ☐ 1
- ☐ 2 *Slightly reduced appetite.*
- ☐ 3
- ☐ 4 *No appetite. Food is tasteless.*
- ☐ 5
- ☐ 6 *Needs persuasion to eat at all.*

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6. Concentration Difficulties

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration. Rate according to intensity, frequency, and degree of incapacity produced.

- ☐ 0 *No difficulties in concentrating.*
- ☐ 1
- ☐ 2 *Occasional difficulties in collecting one's thoughts.*
- ☐ 3
- ☐ 4 *Difficulties in concentrating and sustaining thought which reduces ability to read or hold a conversation.*
- ☐ 5
- ☐ 6 *Unable to read or converse without great difficulty.*

---

7. Lassitude

Representing a difficulty getting started or slowness initiating and performing everyday activities.

- ☐ 0 *Hardly any difficulty in getting started. No sluggishness.*
- ☐ 1
- ☐ 2 *Difficulties in starting activities.*
- ☐ 3
- ☐ 4 *Difficulties in starting simple routine activities which are carried out with effort.*
- ☐ 5
- ☐ 6 *Complete lassitude. Unable to do anything without help.*

DataFax #147 Plate #024 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

MADRS - Continued

8. Inability to Feel

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstances or people is reduced.

- ☐ 0 *Normal interest in the surroundings and in other people.*
- ☐ 1
- ☐ 2 *Reduced ability to enjoy usual interests.*
- ☐ 3
- ☐ 4 *Loss of interest in the surroundings. Loss of feelings for friends and acquaintances.*
- ☐ 5
- ☐ 6 *The experience of being emotionally paralyzed, inability to feel anger, grief, or pleasure and a complete or even painful failure to feel for close relatives and friends.*

---

9. Pessimistic Thoughts

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse, and ruin.

- ☐ 0 *No pessimistic thought.*
- ☐ 1
- ☐ 2 *Fluctuating ideas of failure, self-reproach, or self-depreciation.*
- ☐ 3
- ☐ 4 *Persistent self-accusations, or definite but still rational ideas of guilt or sin. Increasingly pessimistic about the future.*
- ☐ 5
- ☐ 6 *Delusions of ruin, remorse, or unredeemable sin. Self-accusations which are absurd and unshakable.*

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10. Suicidal Thoughts

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts, and preparations for suicide. Suicidal attempts should not in themselves influence the rating.

- ☐ 0 *Enjoys life or takes it as it comes.*
- ☐ 1
- ☐ 2 *Weary of life. Only fleeting suicidal thought.*
- ☐ 3
- ☐ 4 *Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intention.*
- ☐ 5
- ☐ 6 *Explicit plans for suicide when there is an opportunity. Active preparations for suicide.*

Initials or Signature: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

CLINICAL GLOBAL IMPRESSIONS (CGI)

End of Week 32

DataFax #147 Plate #025 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

CLINICAL GLOBAL IMPRESSIONS (CGI)

A. Severity of Illness Considering your total clinical experience with this particular population, how mentally ill is this patient at this time? *(Please check only **ONE**)*

- ☐ 1 *Normal, not at all ill*
- ☐ 2 *Borderline ill*
- ☐ 3 *Mildly ill*
- ☐ 4 *Moderately ill*
- ☐ 5 *Markedly ill*
- ☐ 6 *Severely ill*
- ☐ 7 *Among the most extremely ill patients*

B. Global Improvement *RATE TOTAL IMPROVEMENT WHETHER OR NOT, IN YOUR JUDGEMENT, IT IS DUE ENTIRELY TO DRUG TREATMENT.*

Compared to the patient's condition at DAY 1 (Day 1), how much has the patient changed? *(Please check only **ONE**)*

- ☐ 1 *Very much improved*
- ☐ 2 *Much improved*
- ☐ 3 *Minimally improved*
- ☐ 4 *No change*
- ☐ 5 *Minimally worse*
- ☐ 6 *Much worse*
- ☐ 7 *Very much worse*

C. Efficacy Index *RATE THIS ITEM ON THE BASIS OF DRUG EFFECT ONLY. (Please check only **ONE**)*

ACTIVITY	Tolerability: side effects			
	None	Do not significantly interfere with patient's functioning	Significantly interfere with patient's functioning	Outweigh therapeutic effect
MARKED *Vast improvement, complete or nearly complete remission of all symptoms*	1 ☐	2 ☐	3 ☐	4 ☐
MODERATE *Decided improvement, partial remission of symptoms*	5 ☐	6 ☐	7 ☐	8 ☐
MINIMAL *Slight improvement which does not alter status of care of patient*	9 ☐	10 ☐	11 ☐	12 ☐
UNCHANGED OR WORSE	13 ☐	14 ☐	15 ☐	16 ☐

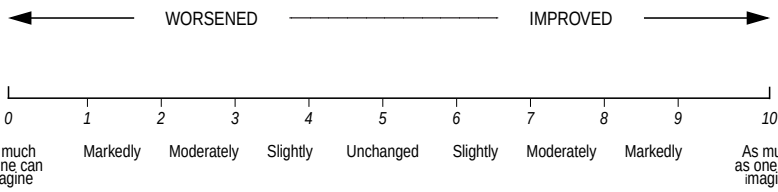
Initials or Signature: _____

DataFax #147 Plate #026 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.*
Subject's Initials ☐☐☐ *F M L*
Date of Evaluation ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*
Randomization Number ☐☐☐☐
Principal Investigator _____ ☐☐☐☐☐
Country US

PATIENT GLOBAL IMPRESSIONS (PGI)

FROM THE STUDY START *(Day 1 of Part 1)* MY GENERAL CONDITION IS:



Using this scale, please write the closest whole number corresponding to your actual situation: ☐☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SF-36 HEALTH SURVEY - *Page 1 of 3*

End of Week 32

DataFax #147 Plate #027 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey

INSTRUCTIONS: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicted. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is: *(check one)*

☐ 1 *Excellent* ☐ 2 *Very Good* ☐ 3 *Good* ☐ 4 *Fair* ☐ 5 *Poor*

2. **Compared to one year ago**, how would you rate your health in general **now**? *(check one)*

☐ 1 *Much better now than one year ago*
☐ 2 *Somewhat better now than one year ago*
☐ 3 *About the same as one year ago*
☐ 4 *Somewhat worse now than one year ago*
☐ 5 *Much worse now than one year ago*

3. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so how much? *(check one box on each line)*

Activities	1 Yes, Limited A Lot	2 Yes, Limited A Little	3 No, Not Limited At All
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐	☐	☐
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
c. Lifting or carrying groceries	☐	☐	☐
d. Climbing several flights of stairs	☐	☐	☐
e. Climbing one flight of stairs	☐	☐	☐
f. Bending, kneeling, or stooping	☐	☐	☐
g. Walking more than a mile	☐	☐	☐
h. Walking several blocks	☐	☐	☐
i. Walking one block	☐	☐	☐
j. Bathing or dressing yourself	☐	☐	☐

SF-36 HEALTH SURVEY - *Page 1 of 3*

Protocol M/2020/0034 (FINAL 20MAY99)

DataFax #147 Plate #028 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

4. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Were limited in the kind of work or other activities	☐	☐
d.	Had difficulty performing the work or other activities *(for example, it took extra effort)*	☐	☐

5. During the **past week**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** *(such as feeling depressed or anxious)*? *(check one box on each line)*

		1 Yes	2 No
a.	Cut down on the amount of time you spent on work or other activities	☐	☐
b.	Accomplished less than you would like	☐	☐
c.	Didn't do work or other activities as carefully as usual	☐	☐

6. During the **past week**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

7. How much **bodily** pain have you had during the **past week?** *(check one)*

☐ 1 *None* ☐ 2 *Very mild* ☐ 3 *Mild* ☐ 4 *Moderate* ☐ 5 *Severe* ☐ 6 *Very severe*

8. During the **past week**, how much did **pain** interfere with your normal work *(including both work outside the home and housework)*? *(check one)*

☐ 1 *Not at all* ☐ 2 *Slightly* ☐ 3 *Moderately* ☐ 4 *Quite a lot* ☐ 5 *Extremely*

DataFax #147 Plate #029 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SF-36 Health Survey - Continued

9. These questions are about how you feel and how things have been with you **during the past week**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past week** *(check one box on each line)*:

	1 All of the time	2 Most of the time	3 A good bit of the time	4 Some of the time	5 A little of the time	6 None of the time
a. Did you feel full of pep?	☐	☐	☐	☐	☐	☐
b. Have you been a very nervous person?	☐	☐	☐	☐	☐	☐
c. Have you felt so down in the dumps that nothing could cheer you up?	☐	☐	☐	☐	☐	☐
d. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
e. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
f. Have you felt downhearted and low?	☐	☐	☐	☐	☐	☐
g. Did you feel worn out?	☐	☐	☐	☐	☐	☐
h. Have you been a happy person?	☐	☐	☐	☐	☐	☐
i. Did you feel tired?	☐	☐	☐	☐	☐	☐

10. During the **past week**, how much of the time has your **physical health or emotional problems** interfered with your social activities *(like visiting with friends, relatives, etc.)*? *(check one)*

☐ 1 *All of the time* ☐ 2 *Most of the time* ☐ 3 *Some of the time* ☐ 4 *A little of the time* ☐ 5 *None of the time*

11. How TRUE or FALSE is each of the following statements for you? *(check one box on each line)*

	1 Definitely True	2 Mostly True	3 Don't Know	4 Mostly False	5 Definitely False
a. I seem to get ill more easily than other people	☐	☐	☐	☐	☐
b. I am as healthy as anybody I know	☐	☐	☐	☐	☐
c. I expect my health to get worse	☐	☐	☐	☐	☐
d. My health is excellent	☐	☐	☐	☐	☐

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 1 of 2***

End of Week 32

DataFax #147 Plate #030 Seq. #232

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ

INSTRUCTIONS: Please describe how you felt DURING THE PAST WEEK. Check the appropriate answer. Do not think long before answering. Work quickly!

	Yes	No
1. Nervous	☐	☐
2. Weary	☐	☐
3. Irritable	☐	☐
4. Cheerful	☐	☐
5. Tense, tensed up	☐	☐
6. Sad, blue	☐	☐
7. Happy	☐	☐
8. Frightened	☐	☐
9. Feeling calm	☐	☐
10. Feeling healthy	☐	☐
11. Losing temper easily	☐	☐
	True	**False**
12. Feeling of not enough air	☐	☐
	Yes	**No**
13. Feeling kind toward people	☐	☐
14. Feeling fit	☐	☐
15. Heavy arms or legs	☐	☐
16. Feeling confident	☐	☐
17. Feeling warm toward people	☐	☐
18. Shaky	☐	☐
	True	**False**
19. No pains anywhere	☐	☐
	Yes	**No**
20. Angry	☐	☐
21. Arms and legs feel strong	☐	☐
22. Appetite poor	☐	☐
23. Feeling peaceful	☐	☐
24. Feeling unworthy	☐	☐
25. Annoyed	☐	☐
26. Feelings of rage	☐	☐
	True	**False**
27. Cannot enjoy yourself	☐	☐
	Yes	**No**
28. Tight head or neck	☐	☐
29. Relaxed	☐	☐
30. Restless	☐	☐
31. Feeling friendly	☐	☐
32. Feelings of hatred	☐	☐
33. Choking feeling	☐	☐
34. Afraid	☐	☐
35. Patient	☐	☐
36. Scared	☐	☐
37. Furious	☐	☐
38. Feeling charitable	☐	☐
39. Feeling guilty	☐	☐
40. Feeling well	☐	☐
41. Feeling of pressure in head or body	☐	☐
42. Worried	☐	☐
43. Contented	☐	☐
44. Weak arms or legs	☐	☐
45. Feeling desperate, terrible	☐	☐
	True	**False**
46. No aches anywhere	☐	☐

KSQ - *Page 1 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

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Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

KELLNER SYMPTOM QUESTIONNAIRE (KSQ) - ***Page 2 of 2***

End of Week 32

DataFax #147 Plate #031 Seq. #232

Subject Number ___ - ___ (*Site No.*) **Subject's Initials** ___ (*F M L*) **Date of Evaluation** ___ (*y y y y m m d d*)

Randomization Number ____ **Principal Investigator** _____ ____ **Country** US

KSQ - Continued

	Yes	No
47. Thinking of death or dying	☐	☐
48. Hot tempered	☐	☐
49. Terrified	☐	☐
50. Feelings of courage	☐	☐
51. Enjoying yourself	☐	☐
52. Breathing is difficult	☐	☐
53. Parts of body numb or tingling	☐	☐
54. Takes a long time to fall asleep	☐	☐
55. Feeling hostile	☐	☐
56. Infuriated	☐	☐
57. Heart beating fast or pounding	☐	☐
58. Depressed	☐	☐
59. Jumpy	☐	☐
60. Feeling like a failure	☐	☐

	True	False
61. Not interested in things	☐	☐

	Yes	No
62. Highly strung	☐	☐

	True	False
63. Cannot relax	☐	☐

	Yes	No
64. Panicky	☐	☐
65. Pressure on head	☐	☐
66. Blaming yourself	☐	☐
67. Thoughts of ending your life	☐	☐
68. Frightening thoughts	☐	☐
69. Enraged	☐	☐
70. Irritated by other people	☐	☐
71. Looking forward to the future	☐	☐
72. Nauseated, sick to stomach	☐	☐
73. Feeling that life is bad	☐	☐
74. Upset bowels or stomach	☐	☐
75. Feeling inferior to others	☐	☐
76. Feeling useless	☐	☐
77. Muscle pains	☐	☐

	True	False
78. No unpleasant feelings in head or body	☐	☐

	Yes	No
79. Headaches	☐	☐
80. Feel like attacking people	☐	☐
81. Shaking with anger	☐	☐
82. Mad	☐	☐
83. Feelings of goodwill	☐	☐
84. Feel like crying	☐	☐
85. Cramps	☐	☐
86. Feeling that something bad will happen	☐	☐
87. Wound up, uptight	☐	☐
88. Get angry quickly	☐	☐
89. Self-confident	☐	☐
90. Resentful	☐	☐
91. Feelings of hopelessness	☐	☐
92. Head pains	☐	☐

KSQ - *Page 2 of 2*

Protocol M/2020/0034 (FINAL 20MAY99)

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

SOCIAL ADAPTATION SELF-EVALUATION SCALE (SASS) - *Page 1 of 2*

End of Week 32

DataFax #147 Plate #032 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS

INSTRUCTIONS: You are asked to answer some simple questions, stating what your opinion is at this moment. Please answer all questions and CHECK one answer for each question.

SASS - Page 1 of 2

Do you have an occupation?..... ☐ *Yes* ☐ *No*

1. If *Yes*, how interested are you in your occupation?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

2. If *No*, how interested are you in your home related activities?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

3. Do you pursue this occupation, these activities with:
   ☐ 3 *A lot of enjoyment?* ☐ 2 *Some enjoyment?* ☐ 1 *Only a little enjoyment?* ☐ 0 *No enjoyment at all?*

4. Are you interested in hobbies/leisure?
   ☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *A little* ☐ 0 *Not at all*

5. Is the quality of your spare time:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

6. How frequently do you seek contacts with your family members *(spouse, children, parents, etc.)*?
   ☐ 3 *Very frequently* ☐ 2 *Frequently* ☐ 1 *Rarely* ☐ 0 *Never*

7. Is the state of relations in your family:
   ☐ 3 *Very good?* ☐ 2 *Good?* ☐ 1 *Fair?* ☐ 0 *Unsatisfactory?*

8. Outside of your family, do you have relationships with:
   ☐ 3 *Many people?* ☐ 2 *Some people?* ☐ 1 *Only a few people?* ☐ 0 *Nobody?*

9. Do you try to form relationships with others:
   ☐ 3 *Very actively?* ☐ 2 *Actively?* ☐ 1 *Moderately actively?* ☐ 0 *In no active way?*

10. How - in general - do you rate your relationships with other people?
    ☐ 3 *Very good* ☐ 2 *Good* ☐ 1 *Fair* ☐ 0 *Unsatisfactory*

Protocol M/2020/0034 (FINAL 20MAY99)

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DataFax #147 Plate #033 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ *Site No.* **Subject's Initials** ☐☐☐ *F M L* **Date of Evaluation** ☐☐☐☐☐☐☐☐ *y y y y m m d d*

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

SASS - Continued

11. What value do you attach to your relationships with others?
☐ 3 *Great value* ☐ 2 *Some value* ☐ 1 *Only a little value* ☐ 0 *No value at all*

12. How often do people in your social circle seek contact with you?
☐ 3 *Very often* ☐ 2 *Often* ☐ 1 *Rarely* ☐ 0 *Never*

13. Do you observe the social rules, good manner, politeness, etc.?
☐ 3 *Always* ☐ 2 *Most of the time* ☐ 1 *Rarely* ☐ 0 *Never*

14. To what extent are you involved in community life *(such as club, church, etc.)*?
☐ 3 *Fully* ☐ 2 *Moderately* ☐ 1 *Slightly* ☐ 0 *Not at all*

15. Do you like searching for information about things, situations and people to improve your understanding of them?
☐ 3 *Very much* ☐ 2 *Moderately* ☐ 1 *Not much* ☐ 0 *Not at all*

16. Are you interested in scientific, technical or cultural information?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Only slightly* ☐ 0 *Not at all*

17. How often do you find it difficult to express your opinions to people?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

18. How often do you feel rejected, excluded from your circle?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

19. How important do you consider your physical appearance?
☐ 3 *Very* ☐ 2 *Moderately* ☐ 1 *Not very much* ☐ 0 *Not at all*

20. To what extent do you have difficulties in managing your resources and income?
☐ 0 *Always* ☐ 1 *Often* ☐ 2 *Sometimes* ☐ 3 *Never*

21. Do you feel able to organize your environment according to your wishes and needs?
☐ 3 *Very much so* ☐ 2 *Moderately* ☐ 1 *Not very* ☐ 0 *Not at all*

Reviewer's Initials: _____

DataFax #147 Plate #035 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐ ☐☐ ☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

RSI

1. Rate each item as it applies in the PAST 4 WEEKS. For each item below, place a mark on the line where you would place yourself.

Example:

infrequent — *very frequent*

a. How frequently do you have pleasurable sexual thoughts?

infrequent — *very frequent*

b. Rate your ability to become sexually excited:

unable — *always able*

c. How frequently do you have desires to initiate sexual activity?

infrequent — *very frequent*

d. How often do you initiate sexual activity?

infrequent — *very frequent*

e. Rate your overall degree of sexual satisfaction attained:

low — *high*

2. How many times on average in the PAST 4 WEEKS did you engage in the following sexual activities?

Masturbation *(solitary or by partner)*:	**Intercourse *(anal or vaginal)*:**	**Oral sex:**
☐ *0 Never*	☐ *0 Never*	☐ *0 Never*
☐ *1 Once per week*	☐ *1 Once per week*	☐ *1 Once per week*
☐ *2 2-4 times per week*	☐ *2 2-4 times per week*	☐ *2 2-4 times per week*
☐ *3 5-10 times per week*	☐ *3 5-10 times per week*	☐ *3 5-10 times per week*
☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*	☐ *4 More than 10 times per week*

DataFax #147 Plate #036 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

MALES ONLY ☐ *N/A (female patient); If N/A is checked, go to question 3b.*

3a. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Spontaneous daytime erections	☐	☐
2. Painful erections	☐	☐
3. Erection when sexually aroused	☐	☐
4. Difficulty getting an erection when sexually stimulated	☐	☐
5. Difficulty maintaining an erection to complete sexual act	☐	☐
6. Waking up from sleep with an erection	☐	☐
7. Requiring more stimuli than usual to achieve an erection	☐	☐
8. Requiring more stimuli than usual to maintain an erection	☐	☐
9. Decreased fullness of erection	☐	☐
10. Increased sensitivity of genitals upon physical stimulation	☐	☐
11. Decreased sensitivity of genitals upon physical stimulation	☐	☐
12. Orgasm	☐	☐
13. Ejaculation	☐	☐
14. Painful orgasm/ejaculation	☐	☐
15. Orgasm without ejaculation	☐	☐
16. Delay in achieving orgasm/ejaculation but eventually doing so	☐	☐
17. Inability to achieve orgasm/ejaculation	☐	☐
18. Orgasm without erection	☐	☐
19. Orgasm occurring during sleep	☐	☐
20. Genital pain during sexual contact	☐	☐
21. Orgasm/ejaculation occurring earlier than desired	☐	☐
22. Experiencing orgasm without sexual provocation *(spontaneously, except in sleep)*	☐	☐
23. Generally decreased intensity of orgasm	☐	☐

Reviewer's Initials: _____

DataFax #147 Plate #037 Seq. #232

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (F M L) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (y y y y m m d d)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

RSI: Section B - Continued

FEMALES ONLY ☐ *N/A (male patient)*

3b. Please check Yes or No for each item as it applies to you over the PAST 4 WEEKS *(one of the 2 choices must be checked for each item).*

	Yes	No
1. Increased sensitivity, other than pain, in breasts upon physical contact	☐	☐
2. Increased sensitivity of genitals, other than pain, upon physical contact	☐	☐
3. Pain in breasts upon physical contact	☐	☐
4. Pain in genitals upon physical contact	☐	☐
5. Decreased sensitivity in breasts upon physical contact	☐	☐
6. Decreased sensitivity in genitals upon physical contact	☐	☐
7. Inadequate swelling or vaginal lubrication during sexual arousal	☐	☐
8. Orgasm	☐	☐
9. Multiple orgasm	☐	☐
10. Difficulty achieving orgasm, but eventually being able to	☐	☐
11. Inability to achieve orgasm	☐	☐
12. Experiencing orgasm without sexual provocation *(spontaneously)*	☐	☐
13. Painful orgasm	☐	☐
14. Decreased intensity or orgasm	☐	☐
15. Involuntary vaginal contractions that prevent vaginal penetration	☐	☐
If Yes check one: ☐ *always* ☐ *intermittently*		
16. Physical pain during sexual activity	☐	☐

What was the first day of your last menstrual period: ☐☐☐☐☐☐☐☐ (y y y y m m d d) ☐ *Not Applicable*

Reviewer's Initials: _____

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

STUDY TERMINATION: DSM-IV 5-AXIS CLINICAL DIAGNOSIS

End of Week 32

DataFax #147 Plate #010 Seq. #232

Subject Number ☐☐-☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

DSM-IV 5-AXIS CLINICAL DIAGNOSIS

AXIS	CODE	NAME
Axis I (DSM-IV)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
Axis II (DSM-IV)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____
Axis III (ICD-9-CM)	☐☐☐.☐☐	_____
	☐☐☐.☐☐	_____

Axis IV ***Please check all that applies:***

- ☐ 1 *Problems with primary support group*
- ☐ 2 *Problems related to the social environment*
- ☐ 3 *Educational problems*
- ☐ 4 *Occupational problems*
- ☐ 5 *Housing problems*
- ☐ 6 *Economic problems*
- ☐ 7 *Problems with access to health care services*
- ☐ 8 *Problems related to interaction with legal system/crime*
- ☐ 9 *Other psychosocial and environmental problems*

Specify: _____

COMMENTS: _____

Axis V Current Score: ☐☐☐

Extreme Mood reactivity present..... ☐ *No* ☐ *Yes*

Rejection sensitivity present..... ☐ *No* ☐ *Yes*

Protocol M/2020/0034 (FINAL 20MAY99)

Initials or Signature _____

PROTOCOL M/2020/0034

STUDY TERMINATION REPORT - PART 2

NOTE: Physical Examination - End of Study

Please complete Physical Examination form at the time of patient Termination, Withdrawal or Study Completion and fax it to DataFax system.
(Physical Examination CRF shrinkwrapped, NOT in CRF binder)

Pharmacia & Upjohn **Protocol M/2020/0034**
Principal Monitor: Saeeduddin Ahmed, M.D.

PHYSICAL EXAMINATION End of Study

Seq. #

DataFax #147 Plate #056

Subject Number ___ - ___ (Site No.) **Subject's Initials** ___ (F M L) **Date of Evaluation** ___ (y y y y m m d d)

Randomization Number ___ **Principal Investigator** _____ ___ **Country** US

INSTRUCTIONS: Check appropriate box to indicate current physical findings. Describe any abnormalities, indicating left or right where applicable. If evaluation of the category is not performed, write "Not Done".

PHYSICAL FINDINGS		
	HEAD AND NECK ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	EENT / MOUTH ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	CHEST / LUNGS ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	HEART ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	BREASTS *(Optional)* ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	BACK / SPINE ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	ABDOMEN ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	EXTREMITIES ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	SKIN ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	LYMPH NODES ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	NERVOUS SYSTEM ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	MENTATION ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	ENDOCRINE ☐ Normal ☐ Abnormal	IF ABNORMAL, BRIEFLY DESCRIBE
	OTHER ABNORMAL PHYSICAL FINDINGS? ☐ No ☐ Yes	IF YES, BRIEFLY DESCRIBE

COMMENTS:

Initials or Signature: _____

PE

PHYSICAL EXAMINATION - End of Study

Protocol M/2020/0034 (FINAL 20MAY99)

Pharmacia & Upjohn

STUDY TERMINATION REPORT - Instructions

DEFINITION OF STUDY TERMINATION REPORT

Study Termination Report refers to the end of study medication period. It is not meant for temporary withdrawal or for the end of follow-up or observation period.

- Check only one option for the patient disposition.
- Always refer back to the *Study Medication* record and double check the day of last study medication. This date must be in accordance with other visit dates (ie, not be before the first visit or after the last visits).
- If the patient did NOT complete the treatment period as defined in the study protocol, choose one primary reason for withdrawal. Try to find out what lies behind the withdrawal, eg, why a consent was withdrawn or a protocol violation happened. Explain in comments section if appropriate. Do not be too quick to enter "Lost to follow-up", patients sometimes return.
- Always choose the most severe reason. Example: If the patient withdrew the informed consent and had side effects that caused problems, check "Adverse event".
- Termination: The *Study Termination Report* page must be completed and submitted for all patients who were assigned Part 2 study medication.

DataFax #147 Plate #041 Seq. #299

Subject Number ☐☐ - ☐☐☐☐ (*Site No.*) **Subject's Initials** ☐☐☐ (*F M L*) **Date of Evaluation** ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Randomization Number ☐☐☐☐ **Principal Investigator** _____ ☐☐☐☐☐ **Country** US

*Choose **one** of the following alternatives to describe the patient disposition:*

☐ *Randomized into Part 2 but has not taken any study medication*

☐ *Randomized into Part 2 and has taken at least one dose of study medication,* *Date of last dose of study medication* ☐☐☐☐☐☐☐☐ (*y y y y m m d d*)

Did patient have a relapse? ☐ *No* ☐ *Yes*

Did the patient complete the 24 weeks of treatment of the study? ☐ *No* ☐ *Yes*

*If **No**, choose **one** primary reason for withdrawal:*

☐ 1 *Adverse event* → ***Fill in / update Adverse Event page***

☐ 2 *Protocol violation* → ***Explain in Comments section below***

☐ 3 *Consent withdrawn* → ***Explain in Comments section if necessary***

☐ 4 *Lost to follow-up*

☐ 5 *Relapse / Failure to respond to Reboxetine according to protocol definition*

☐ 6 *Other, specify:* _____

COMMENTS

Investigator's Signature: _____

PROTOCOL M/2020/0034

ADVERSE EVENT REPORT FORMS

Report only one adverse event per form. If an event stops and later restarts, record the new occurrence on a new form and should be faxed into the Datafax system (1- 888- 272- 7778).

PROTOCOL M/2020/0034

CONCOMITANT MEDICATION FORM

PROTOCOL M/2020/0034

SERIOUS ADVERSE EVENT REPORT FORMS

PROTOCOL M/2020/0034

ADVERSE EVENT FOLLOW-UP REPORT

(As Needed)

Please use this form only to report the course of an unresolved Adverse Event (AE) from the time of the final study visit until the event resolves or is determined to be chronic or stable. Case report forms should be faxed to the DataFax system (1-888-272-7778) upon completion.

PROTOCOL M/2020/0034

EXPOSURE IN UTERO

(As Needed)

Case report form should be faxed to the DataFax system (1-888-272-7778) upon completion.

PROTOCOL M/2020/0034

UNSCHEDULED VISIT

(As Needed)

Hamilton Psychiatric Rating Scale for Depression (25-item HAMD)

Addendum for Hamilton Psychiatric Rating Scale for Depression

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Amsterdam	11065	59	Male	Caucasian	--
	11066	56	Male	Caucasian	RBX
	11133	41	Male	Caucasian	--
	11134	49	Male	Caucasian	--
	11159	48	Female	Caucasian	--
	11160	61	Male	Caucasian	--
	11167	53	Female	Caucasian	--
Barbee	21053	30	Male	Caucasian	--
Clayton	31019	45	Male	Caucasian	RBX
	31020	55	Male	Black	Placebo
	31047	27	Female	Caucasian	--
	31048	46	Female	Caucasian	Placebo

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Clayton	31111	37	Female	Caucasian	--
	31112	44	Female	Caucasian	--
Croft	231001	50	Female	Caucasian	RBX
	231002	40	Female	Caucasian	--
	231079	65	Male	Caucasian	RBX
	231080	55	Female	Caucasian	--
	231119	56	Female	Caucasian	RBX
	231120	54	Female	Caucasian	RBX
	231139	36	Female	Caucasian	--
Delgado	41069	41	Female	Hispanic	RBX
	41070	46	Female	Caucasian	--
	41093	56	Female	Caucasian	RBX

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Delgado	41094	64	Female	Caucasian	RBX
DuBoff	311017	54	Male	Caucasian	RBX
	311018	31	Female	Caucasian	--
	311115	30	Female	Caucasian	Placebo
	311116	44	Female	Caucasian	--
Dunner	211039	53	Female	Caucasian	--
	211040	53	Female	Caucasian	RBX
	211109	43	Male	Caucasian	RBX
	211110	54	Female	Caucasian	Placebo
	211145	41	Male	Caucasian	--
	211146	57	Male	Hispanic	--
	211147	37	Female	Hispanic	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Fava	51113	55	Female	Caucasian	--
	51114	54	Female	Black	--
	51141	30	Female	Caucasian	--
	51142	44	Female	Caucasian	--
Ferguson	241031	61	Male	Caucasian	--
	241032	41	Female	Caucasian	--
	241073	26	Female	Caucasian	--
	241074	21	Female	Caucasian	--
Gilmer	61081	45	Female	Caucasian	--
	61082	56	Female	Caucasian	--
Halbreich	71077	56	Female	Caucasian	--
Helfing	81003	65	Female	Caucasian	Placebo

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Helfing	81004	43	Female	Caucasian	Placebo
	81051	37	Female	Caucasian	--
	81052	39	Female	Caucasian	--
	81075	37	Female	Caucasian	RBX
	81076	23	Female	Caucasian	RBX
	81103	48	Female	Caucasian	Placebo
Hoopes	271021	29	Male	Caucasian	--
	271022	42	Female	Caucasian	RBX
	271045	18	Male	Caucasian	--
Liebowitz	91005	54	Female	Caucasian	--
	91006	44	Female	Caucasian	--
	91035	62	Female	Caucasian	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Liebowitz	91036	38	Male	Hispanic	--
	91097	38	Female	Caucasian	--
	91098	23	Female	Caucasian	--
	91137	40	Male	Caucasian	--
	91138	45	Female	Caucasian	--
Londborg	101009	36	Female	Black	--
	101010	51	Female	Black	--
	101043	31	Female	Caucasian	RBX
	101044	41	Female	Caucasian	Placebo
Lydiard	221033	44	Male	Caucasian	RBX
	221034	40	Female	Caucasian	--
	221129	51	Male	Caucasian	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Lydiard	221130	51	Female	Caucasian	--
McGrath	111057	48	Male	Caucasian	--
	111058	20	Female	American Indian	--
	111171	50	Male	Black	--
Moreines	121007	33	Female	Caucasian	RBX
Munjack	131011	56	Male	Caucasian	Placebo
	131012	42	Female	Caucasian	Placebo
	131071	25	Male	Black	--
	131072	58	Male	Caucasian	--
	131125	34	Female	Black	Placebo
	131126	45	Male	Caucasian	--
	131143	39	Female	Caucasian	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Munjack	131144	33	Female	Caucasian	--
Nelson	141041	55	Female	Caucasian	--
Oldroyd	321055	38	Male	Hispanic	--
	321056	44	Male	Hispanic	--
	321087	55	Male	Caucasian	RBX
Prover	261023	33	Female	Caucasian	RBX
Rapaport	151037	62	Female	Caucasian	Placebo
	151038	52	Male	Caucasian	Placebo
	151085	50	Female	Caucasian	--
	151086	45	Female	Caucasian	--
	151095	49	Male	Caucasian	RBX
	151096	60	Male	Caucasian	Placebo

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Rapaport	151099	52	Female	Caucasian	Placebo
	151100	42	Female	Caucasian	--
	151117	49	Female	Caucasian	--
	151118	47	Male	Caucasian	--
	151153	44	Male	Caucasian	--
Smith	281025	41	Female	Hispanic	--
	281026	46	Female	Caucasian	--
	281101	40	Female	Caucasian	--
	281102	44	Female	Caucasian	Placebo
	281107	61	Female	Caucasian	--
	281108	53	Female	Caucasian	Placebo
Telew	171016	37	Male	Caucasian	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Telew	171027	52	Female	Caucasian	--
Thase	181083	58	Male	Caucasian	RBX
	181084	32	Male	Caucasian	Placebo
	181105	37	Female	Caucasian	--
	181106	28	Male	Other	--
	181135	31	Female	Caucasian	--
	181136	55	Female	Caucasian	--
Trivedi	191013	36	Female	Black	--
	191014	47	Male	Caucasian	RBX
Walsh	171015	45	Female	Caucasian	Placebo
	171028	45	Female	Caucasian	--
	171061	47	Female	Caucasian	--

Note: '--' means patient not randomized

LIST1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Enrolled Patients, Demographics, and Treatment Assignment in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 18, 2001

Inv. Name	Patient Number	Age	Sex	Race	Treatment
Walsh	171062	52	Female	Caucasian	Placebo
	171063	27	Male	Caucasian	Placebo
	171064	21	Female	Hispanic	--
Zajecka	201067	31	Male	Caucasian	RBX
	201068	37	Female	Black	Placebo
	201091	34	Female	Caucasian	--
	201092	41	Female	Black	--
	201123	43	Female	Caucasian	--

Note: '--' means patient not randomized

Table DS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Enrolled
All Enrolled Patients

Date Produced: January 11, 2001

Investigator	Enrolled Patients
Amsterdam, J. (8767)	7
Barbee, J. (11667)	1
Clayton, A. (19375)	6
Croft, H. (18851)	7
Delgado, P. (18800)	4
DuBoff, E. (12718)	4
Dunner, D. (7573)	7
Fava, M. (18802)	4
Ferguson, J. (12411)	4
Gilmer, W. (18833)	2
Halbreich, U. (18229)	1
Helfing, S. (20852)	7

(CONTINUED)

Table DS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Enrolled
All Enrolled Patients

Date Produced: January 11, 2001

Investigator	Enrolled Patients
Hoopes, S. (21074)	3
Liebowitz, M. (12271)	8
Londborg, P. (14378)	4
Lydiard, B. (12449)	4
McGrath, P. (18810)	3
Moreines, R. (19390)	1
Munjack, D. (10067)	8
Nelson, E. (20854)	1
Oldroyd, J. (43014)	3
Prover, S. (21073)	1
Rapaport, M. (14457)	11
Smith, J. (21075)	6

(CONTINUED)

Table DS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Enrolled
All Enrolled Patients

Date Produced: January 11, 2001

Investigator	Enrolled Patients
Telew, N. (19357)	2
Thase, M. (18830)	6
Trivedi, M. (20855)	2
Walsh, T. (43878)	6
Zajecka, J. (12446)	5
Total	128

Table DS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Randomized in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 11, 2001

Investigator	RBX	Placebo	All
Amsterdam, J. (8767)	1	.	1
Clayton, A. (19375)	1	2	3
Croft, H. (18851)	4	.	4
Delgado, P. (18800)	3	.	3
DuBoff, E. (12718)	1	1	2
Dunner, D. (7573)	2	1	3
Helfing, S. (20852)	2	3	5
Hoopes, S. (21074)	1	.	1
Londborg, P. (14378)	1	1	2
Lydiard, B. (12449)	1	.	1
Moreines, R. (19390)	1	.	1

(CONTINUED)

Note: One additional patient (number 91097) was randomized to the reboxetine group by Liebowitz. However, no additional follow-up was obtained from this patient; thus, her data was not included in the tables for Part 2.

Table DS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Randomized in Blinded Medication Phase
All Enrolled Patients

Date Produced: January 11, 2001

Investigator	RBX	Placebo	All
Munjack, D. (10067)	.	3	3
Oldroyd, J. (43014)	1	.	1
Prover, S. (21073)	1	.	1
Rapaport, M. (14457)	1	4	5
Smith, J. (21075)	.	2	2
Thase, M. (18830)	1	1	2
Trivedi, M. (20855)	1	.	1
Walsh, T. (43878)	.	3	3
Zajecka, J. (12446)	1	1	2
Total	24	22	46

Note: One additional patient (number 91097) was randomized to the reboxetine group by Liebowitz. However, no additional follow-up was obtained from this patient; thus, her data was not included in the tables for Part 2.

Table DS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Disposition - Open Label Phase
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
Number of patients enrolled	128	100.0
Number of patients completed 8 weeks	79	61.7
Number of patients discontinued during 8 weeks	49	38.3
Reason of discontinuation:		
- Adverse event	17	13.3
- Protocol violation	8	6.3
- Consent withdrawal	4	3.1
- Lost to follow-up	6	4.7
- Failure to respond to reboxetine	12	9.4
- Other	2	1.6

Table DS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients Disposition - Blinded Medication Phase
All Enrolled Patients

Date Produced: January 11, 2001

	Reboxetine (N=24)		Placebo (N=22)		All (N=46)	
	n	%	n	%	n	%
Number of patients randomized	24	100.0	22	100.0	46	100.0
Number of patients completed 32 weeks			2	9.1	2	4.3
Number of patients discontinued before end of study	24	100.0	20	90.9	44	95.7
Reason of discontinuation:						
- Adverse event	1	4.2			1	2.2
- Protocol violation	1	4.2	1	4.5	2	4.3
- Consent withdrawn	1	4.2	1	4.5	2	4.3
- Lost to follow-up						
- Failure to respond to study medication	13	54.2	13	59.1	26	56.5
- Other/study closure	8	33.3	5	22.7	13	28.3

Note: One patient who was randomized and dropped out before any evaluation was excluded from this table.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Amsterdam	11065	59/Male	No	Lost to follow-up	.	PATIENT LOST TO FOLLOW-UP. FINAL VISIT/CONTACT WITH OUR CLINIC WAS AT WEEK 6 (NO SAFETY ASSESSMENTS REQUESTED AT THAT VISIT)	NO END OF WEEK 8 VISIT PROCEDURES PERFORMED.
		11133	41/Male	No	Failure to respond to study medication	.	.	.
		11134	49/Male	No	Other	PART 2 CLOSED FOR ENROLLMENT ENTER 071	.	.
		11159	48/Female	No	Failure to respond to study medication	.	.	.
		11160	61/Male	No	Other	SEE COMMENT	PART II CLOSED FOR ENROLLMENT. ENTER 071	.
		11167	53/Female	No	Other	SEE COMMENTS	PER SPONSOR, PATIENT ENROLLED DIRECTLY INTO 071. PART II CLOSED FOR ENROLLMENT	.
	Barbee	21053	30/Male	No	Protocol violation	.	PATIENT DISCONTINUED BY THE SPONSOR FOR VISIT SCHEDULE NON-COMPLIANCE DUE TO PATIENT BEING OUT OF THE COUNTRY FOR NEAR A MONTH BETWEEN VISITS 7 AND 8.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Clayton	31047	27/Female	No	Failure to respond to study medication	.	.	.
		31111	37/Female	No	Other	PATIENT'S REQUEST	.	.
		31112	44/Female	No	Other	STUDY TERMINATED EARLY PER SPONSOR	.	.
	Croft	231002	40/Female	No	Protocol violation	.	NONCOMPLIANT WITH DOSING AND VISIT SCHEDULE, ALSO TAKING EXCLUDED CONCOMITANT MEDICATIONS	.
		231080	55/Female	No	Consent withdrawn	.	.	.
		231139	36/Female	No	Other	SPONSOR TERMINATED PROTOCOL	.	.
	Delgado	41070	46/Female	No	Failure to respond to study medication	.	PERMISSION WAS GIVEN FOR PT TO TAPER OFF STUDY MED BY DR.AHMED AT P&U. LATE ENTRY 5/12/00-PT'S END OF STUDY VISIT WAS 1/3/00, SHE WAS ADVISED TO TAKE	REBOXETINE 4MGX3D THEN STOP.SHE RETURNED 10TABS ON 1/3/00 & WAS REDISPENSED THOSE 10TABS.PT RETURNED BOTTLE W/8TABS ON 1/10/00.SHOULD HAVE RETURNED 7

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	DuBoff	311018	31/Female	No	Other	SEE COMMENTS	SUBJECT IS UNABLE TO MAINTAIN STUDY VISIT SCHEDULE	.
		311116	44/Female	No	Lost to follow-up	.	.	.
	Dunner	211039	53/Female	No	Failure to respond to study medication	.	.	.
		211145	41/Male	No	Failure to respond to study medication	.	PATIENT ASKED TO BE WITHDRAWN FROM STUDY FELT HE WAS GETTING WORSE	.
		211146	57/Male	No	Other	PART 2 DISCONTINUED/SPONSOR. 950ECNS005-071 STUDY	.	.
		211147	37/Female	No	Other	SUICIDE ATTEMPT	.	.
	Fava	51113	55/Female	No	Failure to respond to study medication	.	.	.
		51114	54/Female	No	Protocol violation	.	PATIENT HAD A POSITIVE DRUG SCREEN WHEN TESTED AT END OF WEEK 4.	END OF WK 5 CRF'S WERE USED AT FINAL VISIT INSTEAD OF WK 8 CRF'S

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Fava	51141	30/Female	No	Other	M2020-0034 CLOSED-PT. WILL ENTER RESCUE PROTOCOL	.	.
		51142	44/Female	No	Other	PART 2 PORTION OF STUDY CLOSED	PATIENT WILL ENTER 071	.
	Ferguson	241031	61/Male	No	Adverse event	.	PATIENT FILLED OUT END OF WEEK 1 SCALES IN ERROR PATIENT DID FILL OUT RSI OF END OF WEEK 8.	.
		241032	41/Female	No	Consent withdrawn	.	PT. STOPPED TAKING STUDY MEDICATION ON OWN. PT. DID NOT COME BACK TO CLINIC UNTIL JAN 27, 2000. DATE OF LAST DOSE IS CORRECT.	.
		241073	26/Female	No	Failure to respond to study medication	.	.	.
		241074	21/Female	No	Failure to respond to study medication	.	.	.
	Gilmer	61081	45/Female	No	Adverse event	.	.	.
		61082	56/Female	No	Adverse event	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Halbreich	71077	56/Female	No	Adverse event	WITHDREW	PT STATES "THE BIGGEST REASON (FOR STOPPING DRUG) WAS NOT SLEEPING"	END OF WEEK 7 CRFS WERE USED AS FINAL VISIT.
	Helfing	81051	37/Female	No	Failure to respond to study medication	.	.	PATIENT DISCONTINUED AT END OF WEEK 4 VISIT. END OF WEEK 4 CRFS WERE USED.
		81052	39/Female	No	Protocol violation	.	PT MISSED SCHEDULED APPT.DID NOT RETURN PHONE CALLS.PT CALLED 3 WKS LATER & SCHEDULED APPT. FOR FOLLOW-UP.PT HAD GONE MORE THAN 2 DAYS W/O STUDY MED.	PT WITHDRAWN ON 10/15/99. END OF WEEK 2 CRFS WERE USED.
	Hoopes	271021	29/Male	No	Failure to respond to study medication	.	.	.
		271045	18/Male	No	Consent withdrawn	.	PATIENT REQUESTED TO DISCONTINUE TRIAL BECAUSE HE FELT MEDICATION WAS NOT WORKING	.
	Liebowitz	91005	54/Female	No	Failure to respond to study medication	.	.	.
		91006	44/Female	No	Failure to respond to study medication	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Liebowitz	91035	62/Female	No	Failure to respond to study medication	.	.	.
		91036	38/Male	No	Consent withdrawn	.	.	.
		91098	23/Female	No	Adverse event	.	.	.
		91137	40/Male	No	Failure to respond to study medication	.	.	.
		91138	45/Female	No	Failure to respond to study medication	.	.	.
	Londborg	101009	36/Female	No	Failure to respond to study medication	.	.	.
		101010	51/Female	No	Failure to respond to study medication	.	.	.
	Lydiard	221034	40/Female	No	Failure to respond to study medication	.	.	.
		221129	51/Male	No	Adverse event	.	.	.
		221130	51/Female	No	Lost to follow-up	.	SUBJECT NEVER RETURNED FOR WEEK 7 OR EARLY TERMINATION VISIT.	.
	McGrath	111057	48/Male	No	Adverse event	.	COULD NOT TOLERATE URINARY RETENTION AND HEADACHE.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	McGrath	111058	20/Female	No	Failure to respond to study medication	.	.	.
		111171	50/Male	No	Failure to respond to study medication	.	.	.
	Munjack	131071	25/Male	No	Lost to follow-up	.	.	END OF WEEK 5 CRFS USED AT FINAL VISIT INSTEAD OF CRFS FROM END OF WEEK 8
		131072	58/Male	No	Failure to respond to study medication	.	.	.
		131126	45/Male	No	Other	PT ENROLLED IN PROTOCOL # 950ECNS0005-071	.	.
		131143	39/Female	No	Other	PART 2 CLOSED AT THIS TIME	.	.
		131144	33/Female	No	Other	PART II OF STUDY CLOSED PER SPONSOR	.	.
	Nelson	141041	55/Female	No	Failure to respond to study medication	.	.	.
	Oldroyd	321055	38/Male	No	Lost to follow-up	.	DID NOT RETURN TO OFFICE FOR END OF WEEK 8 VISIT. FAILURE TO CONTACT. LAST DOSE IS UNKNOWN.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Oldroyd	321056	44/Male	No	Adverse event	.	.	.
	Rapaport	151085	50/Female	No	Adverse event	.	.	.
		151086	45/Female	No	Adverse event	.	.	.
		151100	42/Female	No	Adverse event	.	.	.
		151117	49/Female	No	Other	STUDY CLOSED OUT, PER SPONSOR	PT. WILL ENTER 071 EXTENSION STUDY.	.
		151118	47/Male	No	Other	STUDY CLOSED OUT, PER SPONSOR	.	.
		151153	44/Male	No	Adverse event	.	PT WITHDREW FROM STUDY DUE TO AE OF DELAYED EJACULATION.	.
	Smith	281025	41/Female	No	Adverse event	.	.	.
		281026	46/Female	No	Failure to respond to study medication	.	.	.
		281101	40/Female	No	Failure to respond to study medication	.	.	.
		281107	61/Female	No	Adverse event	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Telew	171027	52/Female	No	Protocol violation	.	PATIENT MISSED 7 DOSES OF MEDICATION, AS A RESULT SHE WAS DROPPED FOR NON-COMPLIANCE.	.
	Thase	181105	37/Female	No	Failure to respond to study medication	.	.	.
		181106	28/Male	No	Adverse event	.	.	END OF WEEK 2 CRF'S WERE USED AT FINAL VISIT INSTEAD OF CRF'S FROM END OF WEEK 8
		181135	31/Female	No	Protocol violation	.	PT. STOPPED STUDY MED AFTER 4/7/00 DOSE ON HER OWN AND TOOK PROZAC 20MG 4/11/00 SHE STATES SHE SEES HERSELF AS MUCH MORE IRRITABLE BUT DID NOT REPORT	THIS UNTIL 4/11/00
		181136	55/Female	No	Other	CHANGE IN PROTOCOL, PT. WILL ENTER 071 STUDY	.	.
	Trivedi	191013	36/Female	No	Failure to respond to study medication	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Open Label	Walsh	171016	37/Male	No	Lost to follow-up	.	PATIENT WAS LOST TO FOLLOW UP, NO WAY TO ASCERTAIN WHEN LAST DOSE WAS	PATIENT'S LAST VISIT WAS VISIT END OF WEEK 7 ON 09/17/99 NO WEEK 8 CRF'S USED
		171028	45/Female	No	Failure to respond to study medication	.	.	.
		171061	47/Female	No	Adverse event	.	.	.
		171064	21/Female	No	Protocol violation	.	PT WAS TERMINATE EARLY DUE TO LACK OF COMPLIANCE	.
	Zajecka	201091	34/Female	No	Protocol violation	.	PT EVENTLY NON-COMPLIANT IN HER USE OF OPIATE PAIN MEDICATIONS AFTER BEING WARNED NOT TO USE IT IN THE STUDY	.
		201092	41/Female	No	Adverse event	.	.	.
		201123	43/Female	No	Failure to respond to study medication	.	DUE TO PT SCHEDULE, PT CAME FOR EOW8 ON 4-18-00 BUT HAD TO LEAVE FOR WORK AND COMPLETED HAMD, MADRS, VITAL S, AND PHYSICAL EXAM ON 4-20-00 THUS	COMPLETING WEEK 8 VISIT.
Blinded	Amsterdam	11066	56/Male	Yes	Failure to respond to study medication	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Clayton	31019	45/Male	Yes	Failure to respond to study medication	.	.	.
		31048	46/Female	Yes	Consent withdrawn	.	PATIENT WAS TIRED OF CHRONIC CONSTIPATION WHICH WAS A CARRY-OVER FROM WHEN SHE WAS TAKING PROZAC.THIS CONSTIPATION NEVER GOT WORSE WHILE IN THIS STUDY	BUT IT DID NOT IMPROVE.PATIENT DID NOT WANT TO TAKE TREATMENT FOR THE CONSTIPATION BUT WANTED TO STOP STUDY INSTEAD.
	Croft	231001	50/Female	Yes	Consent withdrawn	.	SUBJECT EXPERIENCING SEVERAL AE'S, CONCERNED WITH CARDIAC AE'S. WANTS TO DISCONTINUE, EVALUATION BY CARDIOLOGIST OF CARDIAC AE'S SHOWS THEY ARE NOT	RELATED TO STUDY MEDICATION
		231079	65/Male	Yes	Other	SPONSOR TERMINATED PROTOCOL	.	.
		231119	56/Female	Yes	Failure to respond to study medication	.	.	.
		231120	54/Female	Yes	Failure to respond to study medication	.	.	.
	Delgado	41069	41/Female	Yes	Failure to respond to study medication	.	.	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Delgado	41093	56/Female	Yes	Failure to respond to study medication	.	.	.
		41094	64/Female	Yes	Failure to respond to study medication	.	.	.
	DuBoff	311017	54/Male	Yes	Failure to respond to study medication	.	SUBJECT CHOSE NOT TO CONTINUE BECAUSE OF A RETURN OF DEPRESSION SYMPTOMS	.
		311115	30/Female	Yes	Other	STUDY CLOSURE BY SPONSOR	.	.
	Dunner	211040	53/Female	Yes	Failure to respond to study medication	.	.	.
		211109	43/Male	Yes	Failure to respond to study medication	.	.	.
		211110	54/Female	Yes	Failure to respond to study medication	.	IN ADDITION TO RELAPSE, SITES WERE NOTIFIED BY SPONSOR TO TERMINATE PTS FROM 0034 PROTOCOL	.
	Helfing	81003	65/Female	Yes	Failure to respond to study medication	.	.	PATIENT'S LAST VISIT INFORMATION ARE RECORDED ON END OF WEEK 9 CRFS

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Helfing	81004	43/Female	Yes	Failure to respond to study medication	.	.	PATIENT'S LAST VISIT INFORMATION ARE RECORDED ON END OF WEEK 11 CRFS
		81075	37/Female	Yes	Other	STUDY STOPPED BY SPONSOR	.	.
		81076	23/Female	Yes	Other	SPONSOR TERMINATED STUDY	.	.
		81103	48/Female	Yes	Failure to respond to study medication	.	.	.
	Hoopes	271022	42/Female	Yes	Failure to respond to study medication	.	PT WILL ENROLL IN PROTOCOL 950ECNS0005-071	.
	Londborg	101043	31/Female	Yes	Failure to respond to study medication	.	.	.
		101044	41/Female	Yes	Protocol violation	PT NEEDED PROHIBITED THERAPY	PT TERMINATED DUE TO SPONSOR DIRECTIVE, PT WAS INCORRECTLY PLACED IN PART II AND TOOK EXCLUDED MEDICATION.	.
	Lydiard	221033	44/Male	Yes	Other	STUDY ENDED EARLY BY SPONSOR	PT. MOVED INTO THE OPEN-LABEL PHASE OF STUDY EARLY DUE TO DECISION BY SPONSOR TO END STUDY	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Moreines	121007	33/Female	Yes	Failure to respond to study medication	.	.	.
	Munjack	131011	56/Male	Yes	Other	SPONSOR'S CLOSING PART II	PT COMPLETED 28 WKS OF TREATMENT. HOWEVER DUE TO SPONSOR CLOSING PART II,EARLY TERMINATION CONDUCTED AT END OF WEEK 28 RATHER THAN AT END OF WEEK 32.	.
		131012	42/Female	Yes	Other	STUDY CLOSED PER SPONSOR.	.	.
		131125	34/Female	Yes	Other	SPONSOR TERMINATED PART 2 OF STUDY.	.	.
	Oldroyd	321087	55/Male	Yes	Other	STUDY TERMINATED BY SPONSOR	.	.
	Prover	261023	33/Female	Yes	Protocol violation	.	MISSED END OF WEEK 20 VISIT. DROPPED DUE TO NON-COMPLIANCE. PT DID NOT RETURN FOR FINAL/EXIT VISIT DATE OF LAST DOSE UNKNOWN DATE OF DC 3/13/2000	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Rapaport	151038	52/Male	Yes	Other	SEE BELOW	PATIENT'S END OF WEEK 8 HAMD DID NOT QUALIFY HIM FOR PART II; HOWEVER, PATIENT WAS INADVERTENTLY RANDOMIZED.	PER SPONSOR REQUEST, PATIENT WAS DISCONTINUED FROM STUDY.
		151095	49/Male	Yes	Other	STUDY CLOSED OUT, PER SPONSOR	.	.
		151096	60/Male	Yes	Failure to respond to study medication	.	.	.
		151099	52/Female	Yes	Failure to respond to study medication	.	.	.
	Smith	281102	44/Female	Yes	Failure to respond to study medication	.	.	.
		281108	53/Female	Yes	Failure to respond to study medication	.	.	.
	Thase	181083	58/Male	Yes	Other	PROTOCOL WAS TERMINATED	.	.
		181084	32/Male	Yes	Failure to respond to study medication	.	.	.
	Trivedi	191014	47/Male	Yes	Adverse event	.	SEE SAE. (PATIENT DECLINES FURTHER FOLLOW-UP)	.

Table DS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reason of Discontinuation - Patient Listing
All Enrolled Patients

Date Produced: January 11, 2001

Study Phase	Investigator	Patient	Age/Sex	Randomized	Reason of Discontinuation	Explanation	Comment	Additional Comment
Blinded	Walsh	171015	45/Female	Yes	Failure to respond to study medication	.	.	.
		171062	52/Female	Yes	Failure to respond to study medication	.	PATIENT RELAPSED TODAY WILL BE ENROLLED IN THE 071 STUDY	.
		171063	27/Male	Yes	Failure to respond to study medication	.	PATIENT ENROLLED INTO 0005-071 STUDY	.
	Zajecka	201067	31/Male	Yes	Other	PATIENT ASKED TO BE WITHDRAWN	.	.
		201068	37/Female	Yes	Failure to respond to study medication	.	PT SUFFERED RELAPSE-WAS HESITANT TO CONTINUE IN CONTROLLED STUDY REGIMEN	.

Table DS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Participation by Visit
All Enrolled Patients

Date Produced: January 11, 2001

Visit	RBX	Placebo	All
Day 1	128		128
Week 1	125		125
Week 2	116		116
Week 3	109		109
Week 4	107		107
Week 5	101		101
Week 6	96		96
Week 7	88		88
Week 8	79		79
Week 9	24	22	46
Week 10	23	20	43

(CONTINUED)

Note: Two patients completed 32 weeks of treatment. A third patient (#101044), who was last assessed at around week 30, was listed here in the week 32 visit.

Table DS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Participation by Visit
All Enrolled Patients

Date Produced: January 11, 2001

Visit	RBX	Placebo	All
Week 11	16	15	31
Week 12	14	13	27
Week 13	13	10	23
Week 14	12	9	21
Week 15	10	9	19
Week 16	11	8	19
Week 20	10	7	17
Week 24	4	5	9
Week 28		5	5
Week 32		3	3

Note: Two patients completed 32 weeks of treatment. A third patient (#101044), who was last assessed at around week 30, was listed here in the week 32 visit.

Table DM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Sex	Male	41	32.0
	Female	87	68.0
	Total Reported	128	100.0
Race	Caucasian	108	84.4
	Black	10	7.8
	Hispanic	8	6.3
	American Indian	1	0.8
	Other	1	0.8
	Total Reported	128	100.0
Marital Status	Never married/Single	35	27.3
	Currently married	48	37.5
	Separated	3	2.3
	Windowed	6	4.7

(CONTINUED)

Table DM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Marital Status	Divorced	36	28.1
	Total Reported	128	100.0
Highest Education Level	Middle school or less	3	2.3
	High school diploma	53	41.4
	Technical school certificate	18	14.1
	College degree	33	25.8
	Graduate school degree	21	16.4
	Total Reported	128	100.0
Occupation Status	Managerial and professional specialty occupations	39	30.5
	Technical, sales, and administrative support occupations	37	28.9
	Service Occupations	33	25.8

(CONTINUED)

Table DM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Occupation Status	Precision production, craft, and repair occupations	6	4.7
	Operators, fabricators, and laborers	10	7.8
	Farming, forestry, and fishing occupations	1	0.8
	Never worked	2	1.6
	Total Reported	128	100.0
Living Situation	With spouse	44	34.4
	With family	25	19.5
	Alone	46	35.9
	Non-family	7	5.5
	With significant other (unmarried)	6	4.7
	Total Reported	128	100.0

(CONTINUED)

Table DM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Employment Status	Full-time	64	50.0
	Part-time	20	15.6
	Not employed (by choice)	26	20.3
	Not employed (other)	18	14.1
	Total Reported	128	100.0

Table DM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Age, Weight, and Height
All Enrolled Patients

Date Produced: January 11, 2001

Variable	Statistics	Value
Age (yr)	Mean	44.1
	SD	10.7
	n	128
	Min	18
	Max	65
	Not Reported	0
Weight (lbs)	Mean	175.9
	SD	41.3
	n	128
	Min	101
	Max	333
	Not Reported	0

(CONTINUED)

Table DM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Age, Weight, and Height
All Enrolled Patients

Date Produced: January 11, 2001

Variable	Statistics	Value
Height (in)	Mean	66.1
	SD	3.7
	n	127
	Min	58
	Max	78
	Not Reported	1

Table DM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History
All Enrolled Patients

Date Produced: January 11, 2001

Body System	# Patients with History	%
Heent/Mouth	58	45.3
Cardiovascular	36	28.1
Pulmonary	24	18.8
Gastrointestinal	58	45.3
Renal/Urinary Tract	32	25.0
Musculoskeletal	66	51.6
Neurologic	42	32.8
Dermatologic	37	28.9
Metabolic/Endocrine	25	19.5
Hematologic	19	14.8
Allergic	68	53.1
Other	64	50.0

Table DM4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Findings at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Body System	# Patients with Abnormality	%
Head and neck	6	4.7
Eent/mouth	11	8.6
Chest/Lung	3	2.3
Heart	6	4.7
Breasts	5	3.9
Back/Spine	10	7.8
Abdomen	15	11.7
Extremities	15	11.7
Skin	21	16.4
Lymph Nodes	3	2.3
Nervous System	7	5.5
Mentation	11	8.6

(CONTINUED)

Table DM4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Findings at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Body System	# Patients with Abnormality	%
Endocrine	1	0.8
Other	8	6.3

Table DM5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Psychiatric History
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Treatment Status	In no hospital treatment	28	21.9
	Outpatient	100	78.1
	Total	128	100.0
Ever Hospitalized for This Condition	No	106	82.8
	Yes	22	17.2
	Total	128	100.0
Ever Treated with Psychiatric Medication	No	85	66.4
	Yes	43	33.6
	Total	128	100.0
Relatives Have History	No	34	26.6
	Yes	94	73.4
	Total	128	100.0

Table DM6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Psychotropic Medication Use
All Enrolled Patients

Date Produced: January 11, 2001

Type of Medications	n	%
Benzodiazepines	29	22.7
Anxiolytics other than benzodiazepines	7	5.5
Anti-psychotics	7	5.5
Mood stabilizer including Lithium	17	13.3

Table DM7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients with Family History
All Enrolled Patients

Date Produced: January 11, 2001

Relatives with History of	n	%
No history	34	26.6
Major Depression	84	65.6
Schizophrenia	3	2.3
Bipolar Disorder	9	7.0
Other	29	22.7

Table DM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
All Enrolled Patients

Date Produced: January 11, 2001

Variable	Statistics	Value
Age at onset of first major depressive episode (yrs)	Mean	25.7
	SD	12.9
	n	128
	Min	6
	Max	58
	Not Reported	0
Number of previous episodes	Mean	8.3
	SD	19.3
	n	127
	Min	0
	Max	99
	Not Reported	1

(CONTINUED)

Table DM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
All Enrolled Patients

Date Produced: January 11, 2001

Variable	Statistics	Value
Approximate duration of last episode (years)	Mean	3.7
	SD	7.2
	n	111
	Min	0
	Max	35
	Not Reported	17
Approximate inter-episode duration, if recurrent (years)	Mean	2.1
	SD	3.3
	n	94
	Min	0
	Max	18
	Not Reported	34

(CONTINUED)

Table DM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
All Enrolled Patients

Date Produced: January 11, 2001

Variable	Statistics	Value
Approximate duration of current episode at study start (years)	Mean	4.5
	SD	8.3
	n	128
	Min	0
	Max	46
	Not Reported	0

Table DM9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diagnosis of Depression at Screen
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Present episode best characterized by	Exacerbation of chronic condition	30	23.4
	Recurrence of similar previous conditions	77	60.2
	Significantly diffrent from previous conditions	6	4.7
	First occurence, no previous psychiatric diagnosis	15	11.7
	Total Reported	128	100.0
Precipitating external stress was	Absent	52	40.6
	Probably present	42	32.8
	Definitely present	34	26.6
	Total Reported	128	100.0

Table DM10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Expectation of Patient from Reboxetine Treatment
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
Not effective	3	2.4
Somewhat effective	66	52.4
Very effective	57	45.2
Total reported	126	100.0

Table DM11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV Axis I Diagnosis at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Axis 1 Name at Screen	n	%
Melancholic	60	46.9
Atypical	15	11.7
Mixed	15	11.7
None	36	28.1
Other	2	1.6
Total	128	100.0

Table DM12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV - Axis IV Problems at Screen
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
Problems with primary support group	49	38.3
Problems with related to the social environment	20	15.6
Educational problems	4	3.1
Occupational problems	44	34.4
Housing problems	2	1.6
Economic problems	38	29.7
Problems with access to health care services	10	7.8
Problems related to interaction with legal system/crime	2	1.6
Other psychosocial and environmental problems	25	19.5

Table DM13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV - Axis V Score at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Statistics	Value
Mean	53.5
SD	7.0
n	128
Min	35
Max	68

Table DM14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV - Axis V Clinical Diagnosis at Screen
All Enrolled Patients

Date Produced: January 11, 2001

		n	%
Extreme mood reactivity present	No	115	89.8
	Yes	13	10.2
	Total	128	100.0
Rejection sensitivity present	No	96	75.0
	Yes	31	24.2
	Not Reported	1	0.8
	Total	128	100.0

Table DM15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medications That Helped the Most with Depression - Patients' Response at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Medication	Number of Patients		<25% Improved		25-49% Improved		50-75% Improved		>75% Improved	
	n	%	n	%	n	%	n	%	n	%
Norpramin	1	0.8					1	0.8		
Tofranil	1	0.8			1	0.8				
Vivactil	1	0.8	1	0.8						
Parnate	1	0.8			1	0.8				
Paxil	1	0.8							1	0.8
Prozac	97	75.8	46	35.9	46	35.9	4	3.1	1	0.8
Zoloft	5	3.9			1	0.8	3	2.3	1	0.8
Celexa	1	0.8			1	0.8				
Wellbutin	4	3.1	3	2.3			1	0.8		
Effexor	5	3.9	1	0.8	1	0.8	3	2.3		
Remeron	1	0.8	1	0.8						
Other	1	0.8	1	0.8						

Table DM16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients' Response to Fluoxetine Treatment at Screen
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
Less than 25% improved	63	49.2
Between 25% and 49% improved	65	50.8
Total	128	100.0

Table DM17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Other Psychoactive Drugs Taken During the Month Prior to Screen
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
ADDERALL	1	0.8
ALCOHOL	6	4.7
ALCOHOL - WINE	1	0.8
ALCOHOL(BEER)	1	0.8
AMBIEN	1	0.8
AMITRYPTALINE	2	1.6
ATIVAN	1	0.8
BEER	2	1.6
CLONAZEPAM	1	0.8
COCAINE	1	0.8
DEXEDRINE	1	0.8
ETOH	2	1.6
ETOH-WINE	2	1.6

(CONTINUED)

Table DM17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Other Psychoactive Drugs Taken During the Month Prior to Screen
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
FLUOXETINE	1	0.8
IMIPRIMINE	1	0.8
KLONOPIN	1	0.8
KOLA EXTRACT	1	0.8
LORAZEPAM	1	0.8
NEURONTIN	1	0.8
ONE GLASS WINE	1	0.8
ONE MIXED DRINK	1	0.8
PROZAC	1	0.8
PROZAC/FLUOXETINE	1	0.8
REMERON	1	0.8
SERTRALINE	1	0.8
SERZONE	1	0.8

(CONTINUED)

Table DM17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Other Psychoactive Drugs Taken During the Month Prior to Screen
All Enrolled Patients

Date Produced: January 11, 2001

	n	%
SYNTHROID	1	0.8
TEMAZEPAM	3	2.3
TRAZODONE	7	5.5
VALIUM	4	3.1
VIVACTIL	1	0.8
WELLBUTRIN	1	0.8
WELLBUTRIN SR	1	0.8
WINE	3	2.3
XANAX	2	1.6
ZOLPIDEM	1	0.8

Table DM18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Scores at Screen
All Enrolled Patients

Date Produced: January 11, 2001

Statistics	HAMD-25 Total Score
Mean	29.3
SD	6.7
n	128
Min	15
Max	48

Table DMM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
Randomized Patients

Date Produced: January 11, 2001

		--- RBX --- (N=24)		- Placebo - (N=22)		
		n	%	n	%	P-value
Sex	Male	11	45.8	6	27.3	0.2329
	Female	13	54.2	16	72.7	
	Total Reported	24	100.0	22	100.0	
Race	Caucasian	23	95.8	19	86.4	0.1014
	Black			3	13.6	
	Hispanic	1	4.2			
	Total Reported	24	100.0	22	100.0	
Marital Status	Never married/Single	4	16.7	3	13.6	0.7521
	Currently married	13	54.2	9	40.9	
	Windowed	1	4.2	2	9.1	

(CONTINUED)

Note: P-values are based on Fisher's Exact test.

Table DMM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
Randomized Patients

Date Produced: January 11, 2001

		--- RBX --- (N=24)		- Placebo - (N=22)		
		n	%	n	%	P-value
Marital Status	Divorced	6	25.0	8	36.4	
	Total Reported	24	100.0	22	100.0	
Highest Education Level	Middle school or less			1	4.5	0.5919
	High school diploma	11	45.8	6	27.3	
	Technical school certificate	4	16.7	3	13.6	
	College degree	6	25.0	8	36.4	
	Graduate school degree	3	12.5	4	18.2	
	Total Reported	24	100.0	22	100.0	
Occupation Status	Managerial and professional specialty occupations	7	29.2	6	27.3	0.8367

(CONTINUED)

Note: P-values are based on Fisher's Exact test.

Table DMM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
Randomized Patients

Date Produced: January 11, 2001

		--- RBX --- (N=24)		- Placebo - (N=22)		
		n	%	n	%	P-value
Occupation Status	Technical, sales, and administrative support occupations	10	41.7	9	40.9	
	Service Occupations	6	25.0	3	13.6	
	Precision production, craft, and repair occupations	1	4.2	1	4.5	
	Operators, fabricators, and laborers			1	4.5	
	Farming, forestry, and fishing occupations			1	4.5	
	Never worked			1	4.5	
	Total Reported	24	100.0	22	100.0	
Living Situation	With spouse	11	45.8	7	31.8	0.2217

(CONTINUED)

Note: P-values are based on Fisher's Exact test.

Table DMM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Sex, Race, and Other Categorical Variables
Randomized Patients

Date Produced: January 11, 2001

		--- RBX --- (N=24)		- Placebo - (N=22)		
		n	%	n	%	P-value
Living Situation	With family	6	25.0	3	13.6	
	Alone	6	25.0	11	50.0	
	Non-family			1	4.5	
	With significant other (unmarried)	1	4.2			
	Total Reported	24	100.0	22	100.0	
Employment Status	Full-time	11	45.8	16	72.7	0.2240
	Part-time	4	16.7	1	4.5	
	Not employed (by choice)	6	25.0	2	9.1	
	Not employed (other)	3	12.5	3	13.6	
	Total Reported	24	100.0	22	100.0	

Note: P-values are based on Fisher's Exact test.

Table DMM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Age, Weight, and Height
Randomized Patients

Date Produced: January 12, 2001

Variable	Statistics	- RBX - N=24	- PLB - N=22	P-Value
Age (yr)	Mean	46.7	46.8	0.9624
	SD	11.1	10.5	
	n	24	22	
	Min	23	27	
	Max	65	65	
Weight (lbs)	Mean	177.2	180.6	0.7849
	SD	33.4	49.2	
	n	24	22	
	Min	119	120	
	Max	244	276	
Height (in)	Mean	67.5	67.0	0.5925

(CONTINUED)

Table DMM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Demographics - Age, Weight, and Height
Randomized Patients

Date Produced: January 12, 2001

Variable	Statistics	- RBX - N=24	- PLB - N=22	P-Value
Height (in)	SD	3.8	3.5	
	n	24	22	
	Min	61	58	
	Max	74	72	

Table DMM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History
Randomized Patients

Date Produced: January 11, 2001

Body System	RBX (N=24)		Placebo (N=22)	
	# Patients with History	%	# Patients with History	%
Heent/Mouth	12	50.0	12	54.5
Cardiovascular	7	29.2	10	45.5
Pulmonary	5	20.8	7	31.8
Gastrointestinal	12	50.0	13	59.1
Renal/Urinary Tract	4	16.7	8	36.4
Musculoskeletal	12	50.0	16	72.7
Neurologic	9	37.5	7	31.8
Dermatologic	7	29.2	7	31.8
Metabolic/Endocrine	3	12.5	5	22.7
Hematologic	2	8.3	4	18.2
Allergic	17	70.8	10	45.5

(CONTINUED)

Table DMM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History
Randomized Patients

Date Produced: January 11, 2001

Body System	RBX (N=24)		Placebo (N=22)	
	# Patients with History	%	# Patients with History	%
Other	14	58.3	11	50.0

Table DMM4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Findings at Screen
Randomized Patients

Date Produced: January 11, 2001

Body System	RBX (N=24)		Placebo (N=22)	
	# Patients with Abnormality	%	# Patients with Abnormality	%
Head and neck	3	12.5	1	4.5
Eent/mouth	3	12.5	1	4.5
Chest/Lung	3	12.5		
Heart	1	4.2		
Breasts	1	4.2		
Back/Spine	1	4.2	5	22.7
Abdomen	6	25.0	4	18.2
Extremities	4	16.7	4	18.2
Skin	7	29.2	3	13.6
Lymph Nodes	3	12.5		
Nervous System	3	12.5	1	4.5

(CONTINUED)

Table DMM4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Findings at Screen
Randomized Patients

Date Produced: January 11, 2001

Body System	RBX (N=24)		Placebo (N=22)	
	# Patients with Abnormality	%	# Patients with Abnormality	%
Mentation	2	8.3	4	18.2
Other	2	8.3		

Table DMM5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Psychiatric History
Randomized Patients

Date Produced: January 11, 2001

		--- Reboxetine --- (N=24)		---- Placebo ---- (N=22)	
		n	%	n	%
Treatment Status	In no hospital treatment	3	12.5	9	40.9
	Outpatient	21	87.5	13	59.1
	Total	24	100.0	22	100.0
Ever Hospitalized for This Condition	No	21	87.5	21	95.5
	Yes	3	12.5	1	4.5
	Total	24	100.0	22	100.0
Ever Treated with Psychiatric Medication	No	12	50.0	20	90.9
	Yes	12	50.0	2	9.1
	Total	24	100.0	22	100.0
Relatives Have History	No	6	25.0	4	18.2
	Yes	18	75.0	18	81.8

(CONTINUED)

Table DMM5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Psychiatric History
Randomized Patients

Date Produced: January 11, 2001

		--- Reboxetine --- (N=24)		---- Placebo ---- (N=22)	
		n	%	n	%
Relatives Have History	Total	24	100.0	22	100.0

Table DMM6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Psychotropic Medication Use
Randomized Patients

Date Produced: January 11, 2001

Type of Medications	--- Reboxetine --- (N=24)		---- Placebo ---- (N=22)	
	# Patients with History	%	# Patients with History	%
Benzodiazepines	7	29.2	1	4.5
Anxiolytics other than benzodiazepines	1	4.2		
Anti-psychotics	1	4.2		
Mood stabilizer including Lithium	3	12.5	1	4.5

Table DMM7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients with Family History
Randomized Patients

Date Produced: January 11, 2001

Relatives with History of	--- Reboxetine --- (N=24)		---- Placebo ---- (N=22)	
	n	%	n	%
No history	6	25.0	4	18.2
Major Depression	18	75.0	15	68.2
Bipolar Disorder	2	8.3	1	4.5
Other	5	20.8	7	31.8

Table DMM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
Randomized Patients

Date Produced: January 11, 2001

Variable	Statistics	RBX (N=24)	PLB (N=22)	P-Value
Age at onset of first major depressive episode (yrs)	Mean	25.1	32.7	0.0820
	SD	15.1	13.5	
	n	24	22	
	Min	7	10	
	Max	58	53	
Number of previous episodes	Mean	10.8	3.6	0.2151
	SD	27.4	4.7	
	n	24	22	
	Min	0	0	
	Max	99	19	
Approximate duration of last episode (years)	Mean	4.7	3.0	0.4845
	SD	8.4	7.0	

(CONTINUED)

Table DMM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
Randomized Patients

Date Produced: January 11, 2001

Variable	Statistics	RBX (N=24)	PLB (N=22)	P-Value
Approximate duration of last episode (years)	n	21	19	
	Min	0	0	
	Max	35	30	
	Not Reported	3	3	
Approximate inter-episode duration, if recurrent (years)	Mean	2.5	1.7	0.4716
	SD	4.2	2.6	
	n	19	17	
	Min	0	0	
	Max	18	10	
	Not Reported	5	5	
Approximate duration of current episode at study start (years)	Mean	6.1	2.4	0.1410
	SD	11.6	3.4	

(CONTINUED)

Table DMM8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

History of Depression
Randomized Patients

Date Produced: January 11, 2001

Variable	Statistics	RBX (N=24)	PLB (N=22)	P-Value
Approximate duration of current episode at study start (years)	n	24	22	
	Min	0	0	
	Max	46	12	

Table DMM9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diagnosis of Depression at Screen
Randomized Patients

Date Produced: January 11, 2001

		--- Reboxetine --- (N=24)		---- Placebo ----- (N=22)	
		n	%	n	%
Present episode best characterized by	Exacerbation of chronic condition	4	16.7	2	9.1
	Recurrence of similar previous conditions	18	75.0	15	68.2
	Significantly diffrent from previous conditions	1	4.2	1	4.5
	First occurence, no previous psychiatric diagnosis	1	4.2	4	18.2
	Total Reported	24	100.0	22	100.0
Precipitating external stress was	Absent	12	50.0	5	22.7
	Probably present	6	25.0	10	45.5
	Definitely present	6	25.0	7	31.8
	Total Reported	24	100.0	22	100.0

Table DMM10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Expectation of Patient from Reboxetine Treatment
Randomized Patients

Date Produced: January 11, 2001

	- Reboxetine - (N=24)		-- Placebo --- (N=22)	
	n	%	n	%
Somewhat effective	10	43.5	12	54.5
Very effective	13	56.5	10	45.5
Total reported	23	100.0	22	100.0

Table DMM11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV Axis I Diagnosis at Screen
Randomized Patients

Date Produced: January 11, 2001

Axis 1 Name at Screen	RBX (N=24)		Placebo (N=22)		P-Value
	n	%	n	%	
Melancholic	11	45.8	8	36.4	0.9016
Atypical	4	16.7	3	13.6	
Mixed	3	12.5	4	18.2	
None	6	25.0	7	31.8	
Total	24	100.0	22	100.0	

Table DMM12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV Axis IV Problems at Screen
Randomized Patients

Date Produced: January 11, 2001

Axis IV	-- Reboxetine -- (N=24)		--- Placebo --- (N=22)	
	n	%	n	%
Problems with primary support group	8	33.3	8	36.4
Problems with related to the social environment	4	16.7	5	22.7
Occupational problems	9	37.5	8	36.4
Economic problems	6	25.0	7	31.8
Problems with access to health care services	1	4.2		
Problems related to interaction with legal system/crime			1	4.5
Other psychosocial and environmental problems	3	12.5	5	22.7

Table DMM13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV Axis Score at Screen
Randomized Patients

Date Produced: January 11, 2001

Statistics	- RBX - (N=24)	- PLB - (N=22)
Mean	54.8	53.1
SD	6.3	5.9
n	24	22
Min	38	40
Max	65	60

Table DMM14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV Axis V Clinical Diagnosis at Screen
Randomized Patients

Date Produced: January 11, 2001

		-- Reboxetine -- (N=24)		--- Placebo --- (N=22)	
		n	%	n	%
Extreme mood reactivity present	No	23	95.8	20	90.9
	Yes	1	4.2	2	9.1
	Total	24	100.0	22	100.0
Rejection sensitivity present	No	18	75.0	18	81.8
	Yes	5	20.8	4	18.2
	Not Reported	1	4.2		
	Total	24	100.0	22	100.0

Table DMM15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medications That Helped the Most with Depression - Patients' Response at Screen
Randomized Patients

Date Produced: January 11, 2001

Medication	Group	Number of Patients		<25% Improved		25-49% Improved		50-75% Improved		>75% Improved	
		n	%	n	%	n	%	n	%	n	%
Parnate	RBX (N=24)	1	4.2			1	4.2				
Prozac	RBX (N=24)	20	83.3	9	37.5	10	41.7	1	4.2		
	PLB (N=22)	16	72.7	9	40.9	7	31.8				
Zoloft	RBX (N=24)	1	4.2					1	4.2		
	PLB (N=22)	1	4.5							1	4.5
Wellbutin	RBX (N=24)	1	4.2	1	4.2						
Effexor	PLB (N=22)	1	4.5					1	4.5		

Table DMM16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients' Response to Fluoxetine Treatment at Screen
Randomized Patients

Date Produced: January 11, 2001

	- Reboxetine - (N=24)		-- Placebo --- (N=22)	
	n	%	n	%
Less than 25% improved	11	45.8	10	45.5
Between 25% and 49% improved	13	54.2	12	54.5
Total	24	100.0	22	100.0

Table DMM17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Other Psychoactive Drugs Taken During the Month Prior to Screen
Randomized Patients

Date Produced: January 11, 2001

	- Reboxetine - (N=24)		-- Placebo --- (N=22)	
	n	%	n	%
ALCOHOL	1	4.2	1	4.5
ALCOHOL - WINE			1	4.5
ALCOHOL(BEER)	1	4.2		
AMITRYPTALINE			2	9.1
ETOH-WINE			1	4.5
KOLA EXTRACT			1	4.5
SERZONE	1	4.2		
TRAZODONE	1	4.2	1	4.5
VALIUM	1	4.2		
WELLBUTRIN SR	1	4.2		
WINE	1	4.2		

(CONTINUED)

Table DMM17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Other Psychoactive Drugs Taken During the Month Prior to Screen
Randomized Patients

Date Produced: January 11, 2001

	- Reboxetine - (N=24)		-- Placebo --- (N=22)	
	n	%	n	%
ZOLPIDEM	1	4.2		

Table DMM18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Scores at Baseline (Day 1)
Randomized Patients

Date Produced: January 11, 2001

Statistics	-- RBX -- (N=24)	-- PLB -- (N=22)	P-value
Mean	27.3	26.4	0.5831
SD	4.1	6.1	
n	24	22	
Min	18	13	
Max	36	36	

Table EF1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Number of Patients Responding to Reboxetine in Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

	No. of Patients	% of Patients
Patients Enrolled	128	100.0
Drop-outs due to non-responses	12	9.4
Drop-outs due to related AEs	17	13.3
Drop-outs due to other reasons	20	15.6
Completers of open phase and responders	57	44.5
Completers of open phase and non-responders	22	17.2

A responder is a patient who has at least 50% reduction in HAMD-25 total score at day 57 relative to his baseline total score, and with CGI response of 'very much improved' or 'much improved'.

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	Mean	2.3	2.0	1.8	1.6	1.5	1.5	1.4	1.3	1.4
	SD	0.6	0.8	0.9	0.9	0.9	1.0	1.0	1.1	1.1
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	4	4	4	4
2. Distinct Quality of Mood	Mean	1.3	1.1	1.0	0.9	0.8	0.8	0.8	0.8	0.7
	SD	0.7	0.8	0.8	0.8	0.8	0.7	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
3. Lack of Reactivity	Mean	1.0	0.9	0.7	0.6	0.6	0.5	0.5	0.5	0.5
	SD	0.5	0.6	0.6	0.6	0.6	0.6	0.6	0.7	0.7
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
3. Lack of Reactivity	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
4. Diurnal Variation	Mean	1.0	0.7	0.8	0.6	0.6	0.6	0.5	0.5	0.5
	SD	0.9	0.8	0.8	0.8	0.7	0.7	0.7	0.8	0.7
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
5. Worthlessness	Mean	1.7	1.5	1.4	1.3	1.2	1.2	1.1	1.0	1.0
	SD	0.8	1.0	1.0	1.1	1.0	1.0	1.0	1.1	1.0
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	3	3
6. Guilt	Mean	1.4	1.4	1.2	1.1	1.0	0.9	1.0	0.8	0.8

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	SD	0.8	0.8	0.8	0.9	0.9	0.9	0.9	0.9	0.9
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	3	3
7. Helplessness	Mean	1.6	1.3	1.1	1.1	1.0	1.0	0.9	0.9	0.8
	SD	0.9	0.9	0.9	1.0	1.0	1.0	1.0	1.0	1.0
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	4	4	4	4	4	4	4
8. Hopelessness	Mean	1.5	1.2	1.0	1.0	0.9	0.9	0.9	0.8	0.8
	SD	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
8. Hopelessness	Max	4	4	4	4	4	4	4	4	4
9. Suicide	Mean	0.7	0.5	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	4	4	4	4	4	4	4
10. Early Insomnia	Mean	1.0	0.9	0.9	0.8	0.7	0.7	0.8	0.8	0.8
	SD	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
11. Middle Insomnia	Mean	1.2	1.4	1.3	1.1	1.1	1.1	1.0	1.0	0.9
	SD	0.8	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.9

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
11. Middle Insomnia	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
12. Late Insomnia	Mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.7
	SD	0.8	0.9	0.8	0.8	0.9	0.8	0.9	0.9	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
13. Loss of Appetite	Mean	0.4	0.5	0.4	0.3	0.3	0.3	0.3	0.3	0.3
	SD	0.6	0.6	0.6	0.5	0.5	0.5	0.5	0.5	0.5
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
14. Loss of Weight	Mean	0.3	0.5	0.3	0.2	0.3	0.2	0.2	0.2	0.2
	SD	0.6	0.7	0.6	0.5	0.6	0.5	0.5	0.5	0.5
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
15. Weight Gain	Mean	0.6	0.3	0.3	0.4	0.3	0.4	0.4	0.4	0.3
	SD	0.8	0.6	0.6	0.7	0.6	0.6	0.7	0.6	0.6
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
16. Loss of Energy	Mean	1.6	1.3	1.1	1.0	1.0	1.1	1.0	0.9	0.9
	SD	0.6	0.7	0.7	0.7	0.8	0.7	0.7	0.8	0.8
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
16. Loss of Energy	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
17. Loss of Interest	Mean	1.5	1.3	1.0	1.0	0.9	0.9	0.8	0.8	0.8
	SD	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.8	0.7
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
18. Work and Activities	Mean	2.3	1.9	1.6	1.5	1.6	1.4	1.3	1.2	1.2
	SD	0.9	1.0	1.0	1.1	1.1	1.1	1.1	1.2	1.2
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	4	4
19. Loss of Libido	Mean	1.3	1.1	1.0	1.0	0.9	0.8	0.8	0.8	0.8

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
19. Loss of Libido	SD	0.8	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
20. Psychic Anxiety	Mean	1.7	1.6	1.4	1.3	1.4	1.3	1.2	1.3	1.3
	SD	0.9	0.9	0.9	0.9	1.0	1.0	0.9	1.0	0.9
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	4	4	4	4	4	4	4
21. Somatics Anxiety	Mean	1.2	1.1	1.0	1.0	0.9	1.0	0.9	0.9	0.8
	SD	0.9	0.8	0.9	0.8	0.8	0.9	0.9	0.9	0.9
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
21. Somatics Anxiety	Max	3	4	4	4	4	4	4	4	4
22. Hypochondriasis	Mean	0.5	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	SD	0.7	0.6	0.6	0.5	0.6	0.6	0.5	0.6	0.6
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	3	3
23. Insight	Mean	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.2	0.2	0.1	0.1	0.1	0.1	0.1	0.2	0.1
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	1	1	1	1	1	1	1	1	1
24. Retardation	Mean	0.9	0.7	0.6	0.5	0.6	0.5	0.6	0.5	0.5
	SD	0.8	0.6	0.6	0.7	0.7	0.7	0.6	0.7	0.7

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
24. Retardation	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
25. Agitation	Mean	0.5	0.4	0.4	0.5	0.4	0.4	0.4	0.4	0.4
	SD	0.6	0.6	0.6	0.6	0.5	0.6	0.6	0.6	0.6
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
26. Somatic Symptoms-Gastrointestinal	Mean	0.3	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.2
	SD	0.5	0.5	0.5	0.5	0.4	0.5	0.5	0.5	0.5
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
27. Somatic Symptoms-General	Mean	1.3	1.3	1.0	1.0	1.0	1.0	0.9	0.9	0.9
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.9	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
28. Depersonalization and Derealization	Mean	0.3	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1
	SD	0.6	0.5	0.4	0.4	0.5	0.4	0.4	0.4	0.4
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	2	3	2	2	2	2
29. Paranoid Symptoms	Mean	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
	SD	0.4	0.4	0.3	0.3	0.4	0.4	0.4	0.3	0.4
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
29. Paranoid Symptoms	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
30. Obsessional and Compulsive Symptoms	Mean	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
	SD	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.3	0.3
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	1	2	2	2	1	1	1	1
31. Hypersomnia-Early Bedtime	Mean	0.4	0.4	0.3	0.2	0.2	0.1	0.1	0.1	0.1
	SD	0.7	0.7	0.6	0.6	0.5	0.4	0.5	0.5	0.4
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
32. Hypersomnia-Oversleeping	Mean	0.5	0.4	0.2	0.2	0.2	0.1	0.2	0.2	0.2
	SD	0.8	0.7	0.5	0.5	0.5	0.4	0.5	0.5	0.4
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
33. Hypersomnia-Napping	Mean	0.6	0.6	0.4	0.5	0.5	0.4	0.4	0.3	0.3
	SD	0.8	0.7	0.6	0.7	0.7	0.6	0.6	0.6	0.6
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
34. Increased Appetite	Mean	0.5	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3
	SD	0.7	0.6	0.6	0.6	0.6	0.7	0.6	0.7	0.6
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
34. Increased Appetite	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
35. Psychic Retardation	Mean	0.9	0.7	0.7	0.6	0.6	0.6	0.6	0.6	0.5
	SD	0.8	0.7	0.7	0.7	0.8	0.7	0.7	0.7	0.7
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	2	3	2	2	2	2	2	2
36. Motoric Retardation	Mean	0.9	0.7	0.6	0.6	0.6	0.5	0.5	0.5	0.5
	SD	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	2	2	2	3	3	3	3	3

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	Mean Change	-0.3	-0.5	-0.7	-0.8	-0.8	-0.9	-0.9	-0.9
	SD of Change	0.9	1.0	1.1	1.0	1.1	1.0	1.2	1.2
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	2	2	2	2	2
	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
2. Distinct Quality of Mood	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
	Mean Change	-0.1	-0.2	-0.4	-0.4	-0.5	-0.5	-0.5	-0.5
	SD of Change	0.6	0.8	0.9	0.8	0.8	0.8	0.9	1.0
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	1	2	2

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
2. Distinct Quality of Mood	P-value	0.0259	0.0006	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
3. Lack of Reactivity	Baseline mean	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Mean Change	-0.1	-0.3	-0.4	-0.4	-0.5	-0.4	-0.5	-0.5
	SD of Change	0.6	0.7	0.8	0.8	0.7	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	1	2	2	2	2	2	2
	P-value	0.0962	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
4. Diurnal Variation	Baseline mean	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	Mean Change	-0.3	-0.3	-0.4	-0.5	-0.5	-0.5	-0.5	-0.5
	SD of Change	0.9	1.0	0.9	0.9	1.0	1.0	1.0	1.0
	n	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
4. Diurnal Variation	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0002	0.0012	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
5. Worthlessness	Baseline mean	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
	Mean Change	-0.2	-0.3	-0.4	-0.5	-0.5	-0.6	-0.6	-0.7
	SD of Change	0.8	1.0	1.2	1.1	1.1	1.1	1.1	1.1
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	1	2	3	3	3	3	3	3
	P-value	0.0028	0.0003	0.0001	0.0000	0.0000	0.0000	0.0000	0.0000
6. Guilt	Baseline mean	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
	Mean Change	-0.1	-0.2	-0.4	-0.4	-0.5	-0.4	-0.6	-0.6
	SD of Change	0.7	0.9	1.0	0.9	1.0	1.0	1.0	1.0

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3192	0.0035	0.0001	0.0000	0.0000	0.0000	0.0000	0.0000
7. Helplessness	Baseline mean	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
	Mean Change	-0.3	-0.5	-0.5	-0.6	-0.6	-0.7	-0.7	-0.8
	SD of Change	0.9	1.0	1.1	1.1	1.2	1.1	1.1	1.2
	n	128	128	128	128	128	128	128	128
	Min	-2	-3	-3	-3	-3	-3	-3	-3
	Max	2	2	2	2	2	2	2	2
	P-value	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
8. Hopelessness	Baseline mean	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Mean Change	-0.3	-0.5	-0.5	-0.6	-0.6	-0.6	-0.7	-0.7

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
8. Hopelessness	SD of Change	0.8	1.0	1.0	1.1	1.1	1.2	1.2	1.1
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	1	2	2	3	2	2	2	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
9. Suicide	Baseline mean	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.7
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.3	-0.3	-0.3	-0.3
	SD of Change	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0178	0.0004	0.0001	0.0004	0.0000	0.0002	0.0003	0.0004
10. Early Insomnia	Baseline mean	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
10. Early Insomnia	Mean Change	-0.0	-0.1	-0.2	-0.3	-0.2	-0.2	-0.2	-0.2
	SD of Change	0.8	0.9	0.9	1.0	1.0	1.0	1.0	1.0
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.6482	0.1477	0.0608	0.0033	0.0055	0.0150	0.0158	0.0589
11. Middle Insomnia	Baseline mean	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
	Mean Change	0.2	0.0	-0.1	-0.1	-0.2	-0.2	-0.3	-0.3
	SD of Change	0.9	0.8	0.9	0.9	0.8	0.9	0.9	1.0
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0242	0.5292	0.1311	0.1833	0.0365	0.0141	0.0031	0.0003

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
12. Late Insomnia	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	Mean Change	0.0	0.0	-0.0	-0.0	-0.1	-0.1	-0.1	-0.2
	SD of Change	1.0	1.0	1.0	1.0	1.0	1.0	1.1	1.0
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.7845	0.8605	0.7928	0.5920	0.4817	0.5366	0.2110	0.0285
13. Loss of Appetite	Baseline mean	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	Mean Change	0.1	-0.1	-0.1	-0.2	-0.2	-0.1	-0.1	-0.1
	SD of Change	0.6	0.6	0.6	0.7	0.7	0.6	0.6	0.7
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	2	2	2	2	2

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
13. Loss of Appetite	P-value	0.1233	0.1708	0.0518	0.0041	0.0087	0.0289	0.0259	0.0237
14. Loss of Weight	Baseline mean	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Mean Change	0.2	0.0	-0.1	-0.0	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.8	0.7	0.6	0.7	0.6	0.6	0.6	0.7
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0006	0.8066	0.1239	0.8987	0.3383	0.0685	0.2780	0.3115
15. Weight Gain	Baseline mean	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
	Mean Change	-0.4	-0.3	-0.2	-0.3	-0.2	-0.2	-0.3	-0.3
	SD of Change	0.8	0.9	0.9	0.9	0.9	1.0	0.9	0.9
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
15. Weight Gain	Max	2	2	2	2	2	2	2	2
	P-value	0.0000	0.0002	0.0074	0.0002	0.0045	0.0210	0.0020	0.0005
16. Loss of Energy	Baseline mean	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
	Mean Change	-0.3	-0.5	-0.6	-0.6	-0.6	-0.6	-0.7	-0.7
	SD of Change	0.7	0.7	0.7	0.8	0.8	0.8	0.9	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
17. Loss of Interest	Baseline mean	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Mean Change	-0.2	-0.4	-0.5	-0.5	-0.6	-0.6	-0.7	-0.7
	SD of Change	0.6	0.7	0.7	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
17. Loss of Interest	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	1
	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
18. Work and Activities	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	Mean Change	-0.4	-0.7	-0.8	-0.7	-0.9	-1.0	-1.1	-1.1
	SD of Change	0.9	1.0	1.1	1.1	1.2	1.2	1.3	1.3
	n	128	128	128	128	128	128	128	128
	Min	-3	-4	-4	-4	-4	-4	-4	-4
	Max	2	2	1	1	2	2	2	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
19. Loss of Libido	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
	Mean Change	-0.2	-0.3	-0.4	-0.4	-0.5	-0.5	-0.5	-0.6
	SD of Change	0.7	0.7	0.8	0.7	0.9	0.9	0.9	0.9

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
19. Loss of Libido	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0010	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
20. Psychic Anxiety	Baseline mean	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
	Mean Change	-0.1	-0.2	-0.4	-0.2	-0.4	-0.4	-0.4	-0.4
	SD of Change	0.9	1.0	1.0	1.1	1.2	1.1	1.2	1.1
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	2	2	2	2	2
	P-value	0.4259	0.0140	0.0001	0.0128	0.0003	0.0000	0.0001	0.0000
21. Somatics Anxiety	Baseline mean	1.2	1.2	1.2	1.2	1.2	1.2	1.2	1.2
	Mean Change	-0.1	-0.1	-0.2	-0.2	-0.2	-0.3	-0.3	-0.3

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
21. Somatics Anxiety	SD of Change	0.9	1.1	1.0	1.0	1.0	1.1	1.1	1.1
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	2	3	3	3	3	3	3	3
	P-value	0.2627	0.1985	0.0224	0.0085	0.0285	0.0135	0.0043	0.0007
22. Hypochondriasis	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Mean Change	-0.1	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2
	SD of Change	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	2	1	1	2	2
	P-value	0.1091	0.0055	0.0016	0.0132	0.0020	0.0008	0.0121	0.0024
23. Insight	Baseline mean	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
23. Insight	Mean Change	-0.0	-0.0	-0.1	-0.0	-0.1	-0.0	-0.0	-0.0
	SD of Change	0.2	0.2	0.3	0.2	0.3	0.3	0.3	0.3
	n	128	128	128	128	128	128	128	128
	Min	-1	-1	-1	-1	-1	-1	-1	-1
	Max	1	1	1	1	1	1	1	1
	P-value	0.7070	0.0334	0.0190	0.0334	0.0190	0.0575	0.1322	0.0575
24. Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.4	-0.3	-0.4	-0.4
	SD of Change	0.7	0.7	0.7	0.8	0.7	0.7	0.7	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	1	2	2	2	2	2
	P-value	0.0002	0.0000	0.0000	0.0001	0.0000	0.0000	0.0000	0.0000

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
25. Agitation	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Mean Change	-0.0	-0.1	-0.0	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.5	0.7	0.6	0.6	0.6	0.6	0.6	0.6
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	1
	P-value	0.5185	0.1529	0.7532	0.0564	0.0630	0.0473	0.1410	0.0630
26. Somatic Symptoms-Gastrointestinal	Baseline mean	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Mean Change	0.0	-0.0	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.6	0.5	0.5	0.6	0.5	0.5	0.5	0.5
	n	128	128	128	128	128	128	128	128
	Min	-2	-1	-2	-2	-2	-2	-1	-2
	Max	2	1	1	1	1	1	1	1

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
26. Somatic Symptoms-Gastrointestinal	P-value	0.3678	0.2906	0.1396	0.0074	0.0225	0.0152	0.0100	0.0128
27. Somatic Symptoms-General	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.4	-0.4	-0.4
	SD of Change	0.7	0.8	0.8	0.9	0.9	0.9	0.9	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3874	0.0001	0.0001	0.0004	0.0000	0.0000	0.0000	0.0000
28. Depersonalization and Derealization	Baseline mean	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Mean Change	-0.1	-0.2	-0.2	-0.1	-0.1	-0.2	-0.1	-0.1
	SD of Change	0.5	0.5	0.6	0.6	0.6	0.6	0.6	0.6
	n	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
28. Depersonalization and Derealization	Min	-2	-3	-3	-3	-3	-3	-3	-3
	Max	2	1	1	3	1	1	1	1
	P-value	0.0451	0.0006	0.0029	0.0316	0.0062	0.0023	0.0062	0.0062
29. Paranoid Symptoms	Baseline mean	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
	Mean Change	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	1	1	1	1	1	1	2
	P-value	0.0948	0.1063	0.0585	0.0337	0.0406	0.0406	0.0152	0.0334
30. Obsessional and Compulsive Symptoms	Baseline mean	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
	Mean Change	-0.1	-0.1	-0.1	-0.1	-0.0	-0.1	-0.0	-0.1
	SD of Change	0.4	0.4	0.4	0.5	0.5	0.4	0.5	0.4

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Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
30. Obsessional and Compulsive Symptoms	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	2	2	1	1	1	1
	P-value	0.0491	0.0071	0.1170	0.1948	0.3552	0.0881	0.2408	0.1027
31. Hypersomnia-Early Bedtime	Baseline mean	0.4	0.4	0.4	0.4	0.4	0.4	0.4	0.4
	Mean Change	-0.0	-0.1	-0.2	-0.2	-0.3	-0.3	-0.3	-0.3
	SD of Change	0.7	0.8	0.7	0.7	0.7	0.7	0.7	0.7
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.5550	0.0277	0.0063	0.0003	0.0000	0.0000	0.0001	0.0000
32. Hypersomnia-Oversleeping	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.3	-0.3	-0.3

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
32. Hypersomnia-Oversleeping	SD of Change	0.8	0.7	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0384	0.0000	0.0004	0.0000	0.0000	0.0000	0.0005	0.0000
33. Hypersomnia-Napping	Baseline mean	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
	Mean Change	-0.0	-0.2	-0.2	-0.2	-0.2	-0.2	-0.3	-0.3
	SD of Change	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	1	1
	P-value	0.5099	0.0050	0.0133	0.0198	0.0057	0.0017	0.0001	0.0000
34. Increased Appetite	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
34. Increased Appetite	Mean Change	-0.2	-0.2	-0.2	-0.2	-0.1	-0.2	-0.1	-0.1
	SD of Change	0.6	0.7	0.7	0.8	0.8	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	2	2	2	2	2	2
	P-value	0.0007	0.0020	0.0195	0.0206	0.1493	0.0111	0.0464	0.0365
35. Psychic Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	Mean Change	-0.2	-0.2	-0.3	-0.3	-0.4	-0.3	-0.3	-0.4
	SD of Change	0.7	0.7	0.8	0.8	0.8	0.8	0.7	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-3	-2	-2	-2	-2
	Max	1	2	2	2	2	2	2	2
	P-value	0.0002	0.0011	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

(CONTINUED)

Table EF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
36. Motoric Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.4	-0.4	-0.3	-0.4
	SD of Change	0.6	0.7	0.7	0.7	0.7	0.8	0.8	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-3	-3	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	2
	P-value	0.0035	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	Mean	2.3	2.0	1.7	1.5	1.3	1.3	1.2	1.0	1.0
	SD	0.6	0.8	0.9	0.9	0.9	0.9	0.9	0.9	1.0
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	4	4	3	3
2. Distinct Quality of Mood	Mean	1.3	1.1	1.0	0.8	0.8	0.7	0.7	0.6	0.4
	SD	0.7	0.8	0.8	0.8	0.8	0.7	0.7	0.8	0.7
	n	128	125	115	109	106	99	93	86	77
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
3. Lack of Reactivity	Mean	1.0	0.9	0.6	0.6	0.5	0.4	0.4	0.3	0.2
	SD	0.5	0.6	0.6	0.6	0.6	0.5	0.6	0.6	0.5
	n	128	125	116	109	107	101	95	88	79

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
3. Lack of Reactivity	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
4. Diurnal Variation	Mean	1.0	0.7	0.7	0.6	0.5	0.5	0.4	0.4	0.4
	SD	0.9	0.8	0.8	0.7	0.7	0.7	0.6	0.7	0.6
	n	128	125	116	109	106	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
5. Worthlessness	Mean	1.7	1.4	1.3	1.2	1.0	0.9	0.8	0.8	0.6
	SD	0.8	1.0	0.9	1.1	0.9	0.9	0.9	1.0	0.8
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	3	2
6. Guilt	Mean	1.4	1.3	1.1	1.0	0.9	0.8	0.9	0.6	0.6

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	2	2
7. Helplessness	Mean	1.6	1.3	1.0	1.0	0.9	0.8	0.7	0.6	0.4
	SD	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8	0.7
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	3	3	3	2
8. Hopelessness	Mean	1.5	1.2	0.9	0.9	0.8	0.7	0.7	0.5	0.5
	SD	1.0	1.0	0.9	0.9	0.9	0.8	0.8	0.8	0.7
	n	128	125	116	109	107	100	95	88	79
	Min	0	0	0	0	0	0	0	0	0

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
8. Hopelessness	Max	4	4	3	3	3	3	3	3	3
9. Suicide	Mean	0.7	0.5	0.4	0.3	0.3	0.3	0.3	0.3	0.3
	SD	0.8	0.8	0.7	0.7	0.7	0.6	0.7	0.7	0.6
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	4	3	3	3	3	3	2
10. Early Insomnia	Mean	1.0	1.0	0.8	0.7	0.6	0.7	0.6	0.6	0.7
	SD	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.8	0.8
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
11. Middle Insomnia	Mean	1.2	1.4	1.3	1.1	1.1	1.0	1.0	0.9	0.8
	SD	0.8	0.7	0.8	0.8	0.8	0.8	0.8	0.8	0.8

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
11. Middle Insomnia	n	128	125	115	109	107	100	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
12. Late Insomnia	Mean	0.9	0.9	0.9	0.8	0.8	0.8	0.8	0.6	0.5
	SD	0.8	0.9	0.8	0.8	0.9	0.8	0.9	0.8	0.7
	n	127	125	115	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
13. Loss of Appetite	Mean	0.4	0.5	0.4	0.3	0.2	0.2	0.3	0.2	0.2
	SD	0.6	0.6	0.6	0.5	0.5	0.4	0.5	0.5	0.4
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
14. Loss of Weight	Mean	0.3	0.5	0.3	0.2	0.3	0.2	0.1	0.2	0.2
	SD	0.6	0.7	0.6	0.5	0.6	0.5	0.4	0.5	0.5
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
15. Weight Gain	Mean	0.6	0.3	0.3	0.4	0.3	0.4	0.5	0.4	0.3
	SD	0.8	0.6	0.7	0.7	0.5	0.6	0.7	0.7	0.6
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
16. Loss of Energy	Mean	1.6	1.3	1.1	1.0	1.0	1.0	0.9	0.7	0.7
	SD	0.6	0.7	0.7	0.7	0.8	0.7	0.7	0.8	0.7
	n	128	125	116	109	107	101	95	88	79

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
16. Loss of Energy	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
17. Loss of Interest	Mean	1.5	1.3	1.0	1.0	0.9	0.7	0.7	0.6	0.5
	SD	0.6	0.6	0.6	0.7	0.7	0.7	0.7	0.7	0.7
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
18. Work and Activities	Mean	2.3	1.9	1.5	1.4	1.4	1.2	1.2	0.9	0.8
	SD	0.9	1.0	1.0	1.1	1.0	1.0	1.0	1.0	0.9
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	3	3	3	3
19. Loss of Libido	Mean	1.3	1.1	1.0	1.0	0.9	0.8	0.8	0.8	0.7

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
19. Loss of Libido	SD	0.8	0.9	0.8	0.8	0.8	0.8	0.8	0.8	0.8
	n	127	125	116	109	106	101	94	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
20. Psychic Anxiety	Mean	1.7	1.6	1.4	1.2	1.3	1.1	1.0	1.0	1.0
	SD	0.9	0.9	0.8	0.8	0.9	0.8	0.7	0.9	0.8
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	3	3	3	3
21. Somatics Anxiety	Mean	1.2	1.1	1.0	0.8	0.8	0.8	0.7	0.6	0.5
	SD	0.9	0.8	0.8	0.7	0.7	0.8	0.8	0.7	0.6
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
21. Somatics Anxiety	Max	3	4	3	3	3	3	3	3	2
22. Hypochondriasis	Mean	0.5	0.4	0.3	0.2	0.3	0.3	0.2	0.2	0.1
	SD	0.7	0.6	0.5	0.5	0.5	0.5	0.4	0.4	0.4
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	2	2	2	2	1	2	2
23. Insight	Mean	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.2	0.2	0.1	0.0	0.1	0.0	0.1	0.1	0.1
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	1	1	1	0	1	0	1	1	1
24. Retardation	Mean	0.9	0.7	0.6	0.6	0.6	0.5	0.5	0.4	0.3
	SD	0.8	0.6	0.6	0.7	0.7	0.6	0.6	0.6	0.6

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
24. Retardation	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
25. Agitation	Mean	0.5	0.4	0.3	0.4	0.3	0.3	0.3	0.3	0.2
	SD	0.6	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
26. Somatic Symptoms-Gastrointestinal	Mean	0.3	0.4	0.3	0.3	0.2	0.2	0.2	0.2	0.1
	SD	0.5	0.5	0.5	0.5	0.4	0.4	0.4	0.4	0.3
	n	128	125	116	109	107	100	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	1

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
27. Somatic Symptoms-General	Mean	1.3	1.3	1.0	1.0	1.0	0.9	0.8	0.7	0.7
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
28. Depersonalization and Derealization	Mean	0.3	0.2	0.1	0.1	0.1	0.1	0.1	0.0	0.1
	SD	0.6	0.5	0.4	0.3	0.5	0.3	0.3	0.2	0.2
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	2	3	2	2	1	1
29. Paranoid Symptoms	Mean	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0
	SD	0.4	0.3	0.3	0.3	0.3	0.3	0.2	0.2	0.3
	n	128	125	116	109	107	100	95	87	79

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
29. Paranoid Symptoms	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	1	1	2	1	1	1	2
30. Obsessional and Compulsive Symptoms	Mean	0.2	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
	SD	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.2
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	1	2	2	2	1	1	1	1
31. Hypersomnia-Early Bedtime	Mean	0.4	0.4	0.3	0.3	0.2	0.1	0.2	0.2	0.1
	SD	0.7	0.7	0.6	0.6	0.5	0.4	0.5	0.5	0.4
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
32. Hypersomnia-Oversleeping	Mean	0.5	0.4	0.2	0.2	0.2	0.1	0.2	0.3	0.1
	SD	0.8	0.7	0.5	0.5	0.5	0.3	0.5	0.6	0.4
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
33. Hypersomnia-Napping	Mean	0.6	0.6	0.4	0.4	0.4	0.4	0.4	0.3	0.2
	SD	0.8	0.7	0.6	0.7	0.6	0.6	0.6	0.5	0.5
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
34. Increased Appetite	Mean	0.5	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.3
	SD	0.7	0.6	0.6	0.7	0.6	0.6	0.6	0.7	0.6
	n	128	125	116	109	107	100	95	87	79

(CONTINUED)

Table EF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
34. Increased Appetite	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2
35. Psychic Retardation	Mean	0.9	0.7	0.8	0.6	0.6	0.5	0.5	0.5	0.3
	SD	0.8	0.7	0.8	0.7	0.7	0.6	0.6	0.6	0.6
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	2	3	2	2	2	2	2	2
36. Motoric Retardation	Mean	0.9	0.7	0.6	0.6	0.5	0.4	0.4	0.5	0.3
	SD	0.7	0.7	0.7	0.7	0.7	0.5	0.6	0.6	0.6
	n	128	125	116	109	107	100	95	86	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	2	2	2	3	2	2	2	3

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.2	2.2
	Mean Change	-0.3	-0.6	-0.8	-1.0	-1.0	-1.1	-1.3	-1.2
	SD of Change	0.9	1.0	1.0	0.9	1.0	0.9	1.1	1.1
	n	125	116	109	107	101	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	1	2	1	2	2
	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
2. Distinct Quality of Mood	Baseline mean	1.2	1.2	1.3	1.3	1.3	1.3	1.3	1.3
	Mean Change	-0.1	-0.3	-0.4	-0.5	-0.5	-0.6	-0.7	-0.8
	SD of Change	0.6	0.8	0.9	0.9	0.9	0.9	0.9	1.0
	n	125	115	109	106	99	93	86	77
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	1	2	2

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
2. Distinct Quality of Mood	P-value	0.0259	0.0007	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
3. Lack of Reactivity	Baseline mean	1.0	1.0	1.0	1.0	1.0	0.9	1.0	0.9
	Mean Change	-0.1	-0.4	-0.4	-0.5	-0.6	-0.5	-0.6	-0.7
	SD of Change	0.6	0.7	0.8	0.8	0.7	0.8	0.7	0.6
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	1	2	2	2	2	1	1
	P-value	0.0962	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
4. Diurnal Variation	Baseline mean	1.0	1.0	1.0	1.0	1.0	0.9	1.0	1.0
	Mean Change	-0.3	-0.3	-0.4	-0.5	-0.5	-0.6	-0.6	-0.7
	SD of Change	0.9	1.0	0.9	0.9	0.9	0.9	0.9	1.0
	n	125	116	109	106	101	95	88	79

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
4. Diurnal Variation	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	1	1
	P-value	0.0002	0.0026	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
5. Worthlessness	Baseline mean	1.7	1.7	1.7	1.7	1.7	1.6	1.6	1.6
	Mean Change	-0.2	-0.4	-0.5	-0.7	-0.7	-0.8	-0.9	-1.0
	SD of Change	0.8	1.0	1.2	1.0	1.0	0.9	1.0	0.9
	n	125	116	109	107	101	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	1	2	3	2	2	1	2	1
	P-value	0.0028	0.0001	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
6. Guilt	Baseline mean	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5
	Mean Change	-0.1	-0.3	-0.4	-0.6	-0.6	-0.5	-0.9	-0.9
	SD of Change	0.7	0.9	0.9	0.9	0.9	1.0	0.9	0.9

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	1	1	2	1	2
	P-value	0.3193	0.0009	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
7. Helplessness	Baseline mean	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
	Mean Change	-0.3	-0.6	-0.6	-0.7	-0.8	-0.9	-1.0	-1.1
	SD of Change	0.9	1.0	1.1	1.1	1.2	1.0	1.0	1.0
	n	125	116	109	107	101	95	88	79
	Min	-2	-3	-3	-3	-3	-3	-3	-3
	Max	2	1	2	2	2	1	1	1
	P-value	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
8. Hopelessness	Baseline mean	1.5	1.5	1.5	1.5	1.5	1.4	1.4	1.4
	Mean Change	-0.4	-0.6	-0.6	-0.7	-0.8	-0.8	-0.9	-0.9

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
8. Hopelessness	SD of Change	0.8	1.0	1.1	1.1	1.0	1.1	1.0	0.9
	n	125	116	109	107	100	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	1	2	2	3	2	2	1	1
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
9. Suicide	Baseline mean	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.6
	Mean Change	-0.2	-0.3	-0.3	-0.4	-0.4	-0.3	-0.4	-0.4
	SD of Change	0.7	0.8	0.8	0.8	0.7	0.7	0.8	0.7
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	1	1	1	1	1	1
	P-value	0.0178	0.0002	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
10. Early Insomnia	Baseline mean	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
10. Early Insomnia	Mean Change	-0.0	-0.2	-0.3	-0.4	-0.4	-0.4	-0.4	-0.4
	SD of Change	0.8	0.9	0.9	1.0	0.9	0.9	0.9	0.9
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.6482	0.0324	0.0034	0.0001	0.0001	0.0004	0.0001	0.0008
11. Middle Insomnia	Baseline mean	1.2	1.2	1.2	1.2	1.2	1.2	1.3	1.3
	Mean Change	0.2	0.1	-0.1	-0.1	-0.2	-0.2	-0.3	-0.5
	SD of Change	0.9	0.9	1.0	0.9	0.8	0.9	1.0	1.0
	n	125	115	109	107	100	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0241	0.5248	0.1401	0.1864	0.0791	0.0108	0.0017	0.0001

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
12. Late Insomnia	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	1.0	0.9
	Mean Change	0.0	-0.0	-0.1	-0.1	-0.2	-0.2	-0.3	-0.4
	SD of Change	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	n	124	114	108	106	100	94	87	78
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.6429	0.9274	0.4602	0.2104	0.1441	0.1064	0.0037	0.0003
13. Loss of Appetite	Baseline mean	0.5	0.5	0.4	0.4	0.4	0.4	0.4	0.4
	Mean Change	0.1	-0.1	-0.1	-0.2	-0.2	-0.1	-0.1	-0.2
	SD of Change	0.6	0.6	0.6	0.7	0.7	0.6	0.5	0.6
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	2	2	2	1	1

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
13. Loss of Appetite	P-value	0.1233	0.0858	0.0280	0.0016	0.0034	0.0626	0.0115	0.0148
14. Loss of Weight	Baseline mean	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.2
	Mean Change	0.2	0.0	-0.1	0.0	-0.0	-0.1	-0.0	0.0
	SD of Change	0.8	0.8	0.6	0.7	0.6	0.6	0.6	0.7
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0006	0.9019	0.0936	1.0000	0.6333	0.0770	0.5929	1.0000
15. Weight Gain	Baseline mean	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.7
	Mean Change	-0.4	-0.3	-0.2	-0.3	-0.2	-0.1	-0.2	-0.3
	SD of Change	0.8	0.9	0.9	0.9	0.9	1.0	1.0	0.9
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
15. Weight Gain	Max	2	2	2	2	2	2	2	2
	P-value	0.0000	0.0008	0.0271	0.0003	0.0090	0.2321	0.0363	0.0017
16. Loss of Energy	Baseline mean	1.6	1.6	1.6	1.7	1.6	1.7	1.7	1.6
	Mean Change	-0.3	-0.5	-0.6	-0.7	-0.7	-0.8	-0.9	-0.9
	SD of Change	0.7	0.8	0.7	0.9	0.8	0.8	0.9	0.8
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	1	1	1
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
17. Loss of Interest	Baseline mean	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
	Mean Change	-0.2	-0.5	-0.5	-0.7	-0.8	-0.8	-1.0	-1.0
	SD of Change	0.6	0.7	0.7	0.8	0.8	0.8	0.7	0.7
	n	125	116	109	107	101	95	88	79

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
17. Loss of Interest	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	0
	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
18. Work and Activities	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.4	2.3	2.4
	Mean Change	-0.4	-0.8	-1.0	-0.9	-1.1	-1.2	-1.4	-1.6
	SD of Change	0.9	1.0	1.1	1.1	1.1	1.1	1.1	1.1
	n	125	116	109	107	101	95	88	79
	Min	-3	-4	-4	-4	-4	-4	-4	-4
	Max	2	2	1	1	2	2	1	1
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
19. Loss of Libido	Baseline mean	1.3	1.3	1.4	1.4	1.3	1.4	1.4	1.4
	Mean Change	-0.2	-0.3	-0.4	-0.5	-0.6	-0.6	-0.6	-0.7
	SD of Change	0.7	0.7	0.8	0.7	0.9	0.9	0.9	1.0

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
19. Loss of Libido	n	124	115	108	105	100	93	86	78
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.0010	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
20. Psychic Anxiety	Baseline mean	1.7	1.7	1.7	1.7	1.6	1.7	1.7	1.7
	Mean Change	-0.1	-0.3	-0.5	-0.4	-0.5	-0.7	-0.6	-0.7
	SD of Change	0.9	1.0	1.0	1.1	1.2	1.0	1.2	1.0
	n	125	116	109	107	101	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	1	2	1	2	1
	P-value	0.4259	0.0032	0.0000	0.0005	0.0000	0.0000	0.0000	0.0000
21. Somatics Anxiety	Baseline mean	1.2	1.2	1.1	1.1	1.1	1.1	1.1	1.1
	Mean Change	-0.1	-0.2	-0.3	-0.4	-0.3	-0.4	-0.5	-0.6

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
21. Somatics Anxiety	SD of Change	1.0	1.1	1.0	1.0	1.0	1.1	1.1	0.9
	n	125	116	109	107	101	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	2	3	2	2	2	3	2	1
	P-value	0.2627	0.0627	0.0007	0.0001	0.0021	0.0004	0.0000	0.0000
22. Hypochondriasis	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.4	0.4
	Mean Change	-0.1	-0.2	-0.2	-0.2	-0.2	-0.3	-0.2	-0.3
	SD of Change	0.7	0.7	0.7	0.7	0.7	0.7	0.7	0.8
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	2	1	1	2	2
	P-value	0.1091	0.0127	0.0011	0.0049	0.0010	0.0001	0.0028	0.0010
23. Insight	Baseline mean	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
23. Insight	Mean Change	-0.0	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.2	0.3	0.3	0.2	0.3	0.3	0.3	0.3
	n	125	116	109	107	101	95	88	79
	Min	-1	-1	-1	-1	-1	-1	-1	-1
	Max	1	1	0	0	0	1	1	1
	P-value	0.7071	0.0333	0.0042	0.0075	0.0042	0.0332	0.0958	0.0583
24. Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.4	-0.3	-0.5	-0.5
	SD of Change	0.7	0.7	0.7	0.8	0.7	0.7	0.7	0.8
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	1	2	2	2	1	1
	P-value	0.0002	0.0001	0.0001	0.0008	0.0000	0.0001	0.0000	0.0000

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
25. Agitation	Baseline mean	0.5	0.4	0.5	0.5	0.4	0.5	0.5	0.5
	Mean Change	-0.0	-0.1	-0.0	-0.2	-0.2	-0.2	-0.2	-0.2
	SD of Change	0.6	0.7	0.5	0.6	0.6	0.6	0.6	0.6
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	1
	P-value	0.5186	0.0740	0.3716	0.0034	0.0107	0.0008	0.0155	0.0034
26. Somatic Symptoms-Gastrointestinal	Baseline mean	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Mean Change	0.0	-0.1	-0.1	-0.2	-0.1	-0.1	-0.1	-0.2
	SD of Change	0.6	0.5	0.5	0.6	0.5	0.5	0.5	0.5
	n	125	116	109	107	100	95	88	79
	Min	-2	-1	-2	-2	-2	-2	-1	-2
	Max	2	1	1	1	1	1	1	1

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
26. Somatic Symptoms-Gastrointestinal	P-value	0.3678	0.2752	0.1176	0.0023	0.0188	0.0098	0.0155	0.0065
27. Somatic Symptoms-General	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.2	1.2
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.4	-0.5	-0.5
	SD of Change	0.7	0.8	0.9	0.9	0.9	0.9	0.9	0.8
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3874	0.0001	0.0003	0.0006	0.0000	0.0000	0.0000	0.0000
28. Depersonalization and Derealization	Baseline mean	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2
	Mean Change	-0.1	-0.1	-0.1	-0.1	-0.1	-0.2	-0.2	-0.2
	SD of Change	0.5	0.5	0.6	0.6	0.6	0.6	0.6	0.6
	n	125	116	109	107	100	95	87	79

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
28. Depersonalization and Derealization	Min	-2	-3	-3	-3	-3	-3	-3	-3
	Max	2	1	1	3	1	1	1	1
	P-value	0.0451	0.0027	0.0156	0.1143	0.0272	0.0083	0.0069	0.0063
29. Paranoid Symptoms	Baseline mean	0.2	0.2	0.2	0.1	0.2	0.1	0.1	0.1
	Mean Change	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.5	0.5	0.5	0.4	0.4	0.4	0.4	0.4
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-1
	Max	2	1	1	1	1	1	1	2
	P-value	0.0948	0.1790	0.1452	0.1086	0.0735	0.0896	0.0282	0.1093
30. Obsessional and Compulsive Symptoms	Baseline mean	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
	Mean Change	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1	-0.1
	SD of Change	0.4	0.3	0.5	0.5	0.5	0.4	0.4	0.4

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
30. Obsessional and Compulsive Symptoms	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	1	2	2	1	1	1	1
	P-value	0.0491	0.0041	0.0602	0.2223	0.2995	0.0069	0.1344	0.0116
31. Hypersomnia-Early Bedtime	Baseline mean	0.4	0.4	0.4	0.4	0.4	0.5	0.5	0.5
	Mean Change	-0.0	-0.2	-0.2	-0.3	-0.3	-0.3	-0.3	-0.4
	SD of Change	0.8	0.8	0.8	0.7	0.7	0.7	0.7	0.7
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	1	1
	P-value	0.5550	0.0162	0.0086	0.0002	0.0000	0.0001	0.0004	0.0000
32. Hypersomnia-Oversleeping	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.3	-0.3	-0.4

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
32. Hypersomnia-Oversleeping	SD of Change	0.8	0.7	0.8	0.8	0.8	0.8	0.9	0.9
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	1	2	2	1	2	2	2
	P-value	0.0384	0.0000	0.0005	0.0001	0.0000	0.0003	0.0072	0.0002
33. Hypersomnia-Napping	Baseline mean	0.6	0.6	0.6	0.6	0.6	0.6	0.6	0.6
	Mean Change	-0.0	-0.2	-0.2	-0.2	-0.2	-0.3	-0.3	-0.4
	SD of Change	0.7	0.8	0.8	0.8	0.9	0.9	0.8	0.7
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	1	1
	P-value	0.5100	0.0074	0.0215	0.0319	0.0120	0.0047	0.0005	0.0001
34. Increased Appetite	Baseline mean	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
34. Increased Appetite	Mean Change	-0.2	-0.2	-0.1	-0.2	-0.1	-0.1	-0.1	-0.2
	SD of Change	0.6	0.7	0.8	0.8	0.8	0.8	0.8	0.8
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	2	2	2	2	2	2
	P-value	0.0007	0.0039	0.0519	0.0234	0.1281	0.1092	0.0684	0.0227
35. Psychic Retardation	Baseline mean	1.0	1.0	0.9	1.0	0.9	0.9	0.9	0.9
	Mean Change	-0.2	-0.2	-0.3	-0.4	-0.4	-0.4	-0.4	-0.6
	SD of Change	0.7	0.7	0.9	0.8	0.7	0.8	0.7	0.8
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-3	-2	-2	-2	-2
	Max	1	2	2	2	2	2	2	2
	P-value	0.0002	0.0024	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

(CONTINUED)

Table EF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Items - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Items		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
36. Motoric Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.8	0.8
	Mean Change	-0.2	-0.2	-0.3	-0.4	-0.5	-0.4	-0.4	-0.5
	SD of Change	0.6	0.7	0.7	0.7	0.7	0.8	0.7	0.8
	n	125	116	109	107	100	95	86	79
	Min	-2	-2	-3	-3	-2	-2	-2	-2
	Max	1	1	1	1	1	1	1	2
	P-value	0.0035	0.0016	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores: Mean Total Scores by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-17	Mean	17.8	16.6	14.4	13.3	13.3	12.6	12.3	11.8	11.5
	SD	5.4	5.5	6.0	6.8	6.8	7.1	7.3	7.6	7.8
	n	128	128	128	128	128	128	128	128	128
	Min	6	6	2	0	1	0	0	0	0
	Max	34	37	37	37	37	37	37	37	37
HAMD-25	Mean	28.4	25.1	21.9	20.2	19.7	18.9	18.4	17.6	17.1
	SD	7.3	8.3	9.2	10.4	10.5	10.8	10.9	11.8	12.0
	n	128	128	128	128	128	128	128	128	128
	Min	13	7	3	1	1	0	0	0	0
	Max	49	53	53	53	53	53	53	53	53
HAMD-28	Mean	23.9	21.0	18.3	17.1	16.8	16.0	15.6	15.2	14.7
	SD	6.3	6.7	7.6	8.7	8.6	8.7	8.9	9.6	9.8
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-28	Min	11	6	2	0	1	0	0	0	0
	Max	43	46	46	46	46	46	46	46	46

Table EF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-17	Baseline Mean	17.8	17.8	17.8	17.8	17.8	17.8	17.8	17.8
	Mean Change	-1.2	-3.4	-4.5	-4.5	-5.2	-5.5	-6.0	-6.2
	SD of Change	4.9	6.4	7.1	7.0	7.4	7.5	8.1	8.1
	n	128	128	128	128	128	128	128	128
	Min	-24	-26	-28	-27	-27	-28	-28	-28
	Max	9	11	12	12	14	14	14	14
	P-value	0.0074	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
HAMD-25	Baseline Mean	28.4	28.4	28.4	28.4	28.4	28.4	28.4	28.4
	Mean Change	-3.3	-6.5	-8.1	-8.7	-9.5	-10.0	-10.7	-11.3
	SD of Change	7.4	9.4	10.5	10.6	10.9	11.2	12.3	12.2
	n	128	128	128	128	128	128	128	128
	Min	-38	-39	-39	-41	-42	-42	-44	-44
	Max	15	11	16	16	17	17	17	17

(CONTINUED)

Table EF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores - Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-25	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
HAMD-28	Baseline Mean	23.9	23.9	23.9	23.9	23.9	23.9	23.9	23.9
	Mean Change	-2.8	-5.5	-6.8	-7.1	-7.8	-8.2	-8.7	-9.2
	SD of Change	6.1	7.9	8.7	8.6	8.9	9.0	9.8	9.8
	n	128	128	128	128	128	128	128	128
	Min	-30	-32	-34	-34	-32	-34	-33	-33
	Max	15	14	14	16	14	14	14	14
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores: Mean Total Scores by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-17	Mean	17.8	16.6	13.9	12.3	12.1	10.9	10.7	9.2	8.5
	SD	5.5	5.5	5.7	6.2	6.1	6.2	6.2	6.1	5.6
	n	125	125	115	109	106	99	93	86	79
	Min	6	6	2	0	1	0	0	0	0
	Max	34	37	31	27	29	31	27	29	27
HAMD-25	Mean	28.4	25.0	20.9	18.7	17.8	16.3	15.8	13.6	12.1
	SD	7.4	8.3	8.8	9.6	9.5	9.3	9.4	9.7	8.6
	n	125	125	114	109	104	97	91	85	77
	Min	13	7	3	1	1	0	0	0	0
	Max	49	53	48	42	45	45	42	46	37
HAMD-28	Mean	23.9	21.0	17.8	16.0	15.4	14.1	13.8	12.1	10.8
	SD	6.3	6.6	7.3	8.0	7.8	7.4	7.6	8.0	7.1
	n	125	125	115	109	105	98	93	85	79

(CONTINUED)

Table EF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores: Mean Total Scores by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-28	Min	11	6	2	0	1	0	0	0	0
	Max	43	46	37	35	38	36	33	36	33

Table EF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-17	Baseline Mean	17.9	17.8	17.8	17.9	17.6	18.0	17.7	17.6
	Mean Change	-1.3	-3.9	-5.4	-5.9	-6.8	-7.4	-8.5	-9.0
	SD of Change	4.9	6.5	6.7	6.6	6.6	6.6	7.1	6.3
	n	122	112	106	103	96	91	84	77
	Min	-24	-26	-28	-27	-26	-28	-28	-27
	Max	9	11	12	6	14	3	4	5
	P-value	0.0045	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
HAMD-25	Baseline Mean	28.4	28.3	28.2	28.4	28.1	28.4	28.2	27.9
	Mean Change	-3.5	-7.4	-9.6	-10.7	-11.9	-12.8	-14.6	-15.8
	SD of Change	7.5	9.5	10.0	9.9	9.9	10.0	10.7	9.1
	n	122	111	106	101	94	89	83	75
	Min	-38	-39	-39	-41	-42	-42	-44	-41
	Max	15	11	16	10	17	8	9	7

(CONTINUED)

Table EF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD Total Scores - Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Total Scores		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
HAMD-25	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
HAMD-28	Baseline Mean	24.0	23.8	23.8	23.9	23.6	23.9	23.6	23.6
	Mean Change	-3.1	-6.0	-7.8	-8.6	-9.7	-10.2	-11.5	-12.8
	SD of Change	6.1	8.0	8.3	8.3	8.1	8.3	9.2	7.9
	n	122	112	106	102	95	91	83	77
	Min	-30	-32	-34	-34	-32	-34	-33	-31
	Max	15	14	12	16	14	6	13	11
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Subscale Total	Mean	9.8	8.8	7.6	7.0	7.1	6.6	6.4	6.0	6.0
	SD	2.7	3.0	3.4	3.7	3.9	3.8	3.8	4.2	4.2
	n	128	128	128	128	128	128	128	128	128
	Min	3	2	1	0	0	0	0	0	0
	Max	15	15	15	15	15	15	15	15	15
1. Depressed Mood	Mean	2.3	2.0	1.8	1.6	1.5	1.5	1.4	1.3	1.4
	SD	0.6	0.8	0.9	0.9	0.9	1.0	1.0	1.1	1.1
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	4	4	4	4
6. Guilt	Mean	1.4	1.4	1.2	1.1	1.0	0.9	1.0	0.8	0.8
	SD	0.8	0.8	0.8	0.9	0.9	0.9	0.9	0.9	0.9
	n	128	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	3	3
18. Work & activities	Mean	2.3	1.9	1.6	1.5	1.6	1.4	1.3	1.2	1.2
	SD	0.9	1.0	1.0	1.1	1.1	1.1	1.1	1.2	1.2
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	4	4	4	4
24. Retardation	Mean	0.9	0.7	0.6	0.5	0.6	0.5	0.6	0.5	0.5
	SD	0.8	0.6	0.6	0.7	0.7	0.7	0.6	0.7	0.7
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
20. Psychic anxiety	Mean	1.7	1.6	1.4	1.3	1.4	1.3	1.2	1.3	1.3
	SD	0.9	0.9	0.9	0.9	1.0	1.0	0.9	1.0	0.9
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	4	4	4	4	4	4	4
27. General somatic symtoms	Mean	1.3	1.3	1.0	1.0	1.0	1.0	0.9	0.9	0.9
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.9	0.8
	n	128	128	128	128	128	128	128	128	128
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

Table EF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Subscale Total	Baseline mean	9.8	9.8	9.8	9.8	9.8	9.8	9.8	9.8
	Mean Change	-1.0	-2.3	-2.9	-2.7	-3.2	-3.4	-3.9	-3.9
	SD of Change	2.6	3.6	3.8	3.9	3.9	3.9	4.3	4.4
	n	128	128	128	128	128	128	128	128
	Min	-11	-14	-14	-15	-14	-15	-15	-15
	Max	6	6	6	6	6	6	6	6
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1. Depressed Mood	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	Mean Change	-0.3	-0.5	-0.7	-0.8	-0.8	-0.9	-0.9	-0.9
	SD of Change	0.9	1.0	1.1	1.0	1.1	1.0	1.2	1.2
	n	128	128	128	128	128	128	128	128
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	2	2	2	2	2

(CONTINUED)

Table EF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
6. Guilt	Baseline mean	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
	Mean Change	-0.1	-0.2	-0.4	-0.4	-0.5	-0.4	-0.6	-0.6
	SD of Change	0.7	0.9	1.0	0.9	1.0	1.0	1.0	1.0
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3192	0.0035	0.0001	0.0000	0.0000	0.0000	0.0000	0.0000
18. Work & activities	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.3	2.3
	Mean Change	-0.4	-0.7	-0.8	-0.7	-0.9	-1.0	-1.1	-1.1
	SD of Change	0.9	1.0	1.1	1.1	1.2	1.2	1.3	1.3
	n	128	128	128	128	128	128	128	128
	Min	-3	-4	-4	-4	-4	-4	-4	-4

(CONTINUED)

Table EF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
18. Work & activities	Max	2	2	1	1	2	2	2	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
24. Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.4	-0.3	-0.4	-0.4
	SD of Change	0.7	0.7	0.7	0.8	0.7	0.7	0.7	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	1	2	2	2	2	2
	P-value	0.0002	0.0000	0.0000	0.0001	0.0000	0.0000	0.0000	0.0000
20. Psychic anxiety	Baseline mean	1.7	1.7	1.7	1.7	1.7	1.7	1.7	1.7
	Mean Change	-0.1	-0.2	-0.4	-0.2	-0.4	-0.4	-0.4	-0.4
	SD of Change	0.9	1.0	1.0	1.1	1.2	1.1	1.2	1.1
	n	128	128	128	128	128	128	128	128

(CONTINUED)

Table EF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
20. Psychic anxiety	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	2	2	2	2	2
	P-value	0.4259	0.0140	0.0001	0.0128	0.0003	0.0000	0.0001	0.0000
27. General somatic symtoms	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.3	1.3
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.4	-0.4	-0.4
	SD of Change	0.7	0.8	0.8	0.9	0.9	0.9	0.9	0.8
	n	128	128	128	128	128	128	128	128
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3874	0.0001	0.0001	0.0004	0.0000	0.0000	0.0000	0.0000

Table EF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Subscale Total	Mean	9.8	8.8	7.3	6.5	6.5	5.7	5.6	4.5	4.4
	SD	2.7	2.9	3.4	3.6	3.7	3.4	3.4	3.5	3.4
	n	128	125	116	109	107	100	95	87	79
	Min	3	2	1	0	0	0	0	0	0
	Max	15	15	15	14	15	14	14	13	14
1. Depressed Mood	Mean	2.3	2.0	1.7	1.5	1.3	1.3	1.2	1.0	1.0
	SD	0.6	0.8	0.9	0.9	0.9	0.9	0.9	0.9	1.0
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	4	4	3	3
6. Guilt	Mean	1.4	1.3	1.1	1.0	0.9	0.8	0.9	0.6	0.6
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.7
	n	128	125	116	109	107	101	95	88	79

(CONTINUED)

Table EF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
6. Guilt	Min	0	0	0	0	0	0	0	0	0
	Max	3	3	3	3	3	3	3	2	2
18. Work & activities	Mean	2.3	1.9	1.5	1.4	1.4	1.2	1.2	0.9	0.8
	SD	0.9	1.0	1.0	1.1	1.0	1.0	1.0	1.0	0.9
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	4	4	4	4	4	3	3	3	3
24. Retardation	Mean	0.9	0.7	0.6	0.6	0.6	0.5	0.5	0.4	0.3
	SD	0.8	0.6	0.6	0.7	0.7	0.6	0.6	0.6	0.6
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

(CONTINUED)

Table EF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
20. Psychic anxiety	Mean	1.7	1.6	1.4	1.2	1.3	1.1	1.0	1.0	1.0
	SD	0.9	0.9	0.8	0.8	0.9	0.8	0.7	0.9	0.8
	n	128	125	116	109	107	101	95	88	79
	Min	0	0	0	0	0	0	0	0	0
	Max	3	4	3	3	3	3	3	3	3
27. General somatic symtoms	Mean	1.3	1.3	1.0	1.0	1.0	0.9	0.8	0.7	0.7
	SD	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.8	0.7
	n	128	125	116	109	107	100	95	87	79
	Min	0	0	0	0	0	0	0	0	0
	Max	2	2	2	2	2	2	2	2	2

Table EF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Subscale Total	Baseline mean	9.9	9.9	9.8	9.9	9.8	9.9	9.8	9.8
	Mean Change	-1.1	-2.5	-3.3	-3.4	-4.1	-4.3	-5.3	-5.4
	SD of Change	2.7	3.6	3.7	3.8	3.6	3.5	3.9	3.8
	n	125	116	109	107	100	95	87	79
	Min	-11	-14	-14	-15	-14	-15	-15	-15
	Max	6	6	5	5	6	3	3	3
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
1. Depressed Mood	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.3	2.2	2.2
	Mean Change	-0.3	-0.6	-0.8	-1.0	-1.0	-1.1	-1.3	-1.2
	SD of Change	0.9	1.0	1.0	0.9	1.0	0.9	1.1	1.1
	n	125	116	109	107	101	95	88	79
	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	1	2	1	2	2

(CONTINUED)

Table EF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
1. Depressed Mood	P-value	0.0005	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
6. Guilt	Baseline mean	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.5
	Mean Change	-0.1	-0.3	-0.4	-0.6	-0.6	-0.5	-0.9	-0.9
	SD of Change	0.7	0.9	0.9	0.9	0.9	1.0	0.9	0.9
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	1	1	2	1	2
	P-value	0.3193	0.0009	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
18. Work & activities	Baseline mean	2.3	2.3	2.3	2.3	2.3	2.4	2.3	2.4
	Mean Change	-0.4	-0.8	-1.0	-0.9	-1.1	-1.2	-1.4	-1.6
	SD of Change	0.9	1.0	1.1	1.1	1.1	1.1	1.1	1.1
	n	125	116	109	107	101	95	88	79
	Min	-3	-4	-4	-4	-4	-4	-4	-4

(CONTINUED)

Table EF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
18. Work & activities	Max	2	2	1	1	2	2	1	1
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
24. Retardation	Baseline mean	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.8
	Mean Change	-0.2	-0.3	-0.3	-0.3	-0.4	-0.3	-0.5	-0.5
	SD of Change	0.7	0.7	0.7	0.8	0.7	0.7	0.7	0.8
	n	125	116	109	107	101	95	88	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	1	2	1	2	2	2	1	1
	P-value	0.0002	0.0001	0.0001	0.0008	0.0000	0.0001	0.0000	0.0000
20. Psychic anxiety	Baseline mean	1.7	1.7	1.7	1.7	1.6	1.7	1.7	1.7
	Mean Change	-0.1	-0.3	-0.5	-0.4	-0.5	-0.7	-0.6	-0.7
	SD of Change	0.9	1.0	1.0	1.1	1.2	1.0	1.2	1.0
	n	125	116	109	107	101	95	88	79

(CONTINUED)

Table EF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Melancholia Subscale: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

HAMD-28 Melancholia Subscale		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
20. Psychic anxiety	Min	-3	-3	-3	-3	-3	-3	-3	-3
	Max	3	2	2	1	2	1	2	1
	P-value	0.4259	0.0032	0.0000	0.0005	0.0000	0.0000	0.0000	0.0000
27. General somatic symtoms	Baseline mean	1.3	1.3	1.3	1.3	1.3	1.3	1.2	1.2
	Mean Change	-0.1	-0.3	-0.3	-0.3	-0.4	-0.4	-0.5	-0.5
	SD of Change	0.7	0.8	0.9	0.9	0.9	0.9	0.9	0.8
	n	125	116	109	107	100	95	87	79
	Min	-2	-2	-2	-2	-2	-2	-2	-2
	Max	2	2	2	2	2	2	2	2
	P-value	0.3874	0.0001	0.0003	0.0006	0.0000	0.0000	0.0000	0.0000

Table EF14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness, Open Phase - ITT - LOCF
All Enrolled Patients

Date Produced: January 12, 2001

	Baseline		Week 1		Week 2		Week 4		Week 6		Week 8/Final	
	n	%	n	%	n	%	n	%	n	%	n	%
Normal, not at all ill			1	0.8	2	1.6	3	2.3	8	6.3	12	9.4
Borderline ill			1	0.8	8	6.3	17	13.3	22	17.2	37	28.9
Mildly ill	3	2.3	13	10.2	27	21.1	34	26.6	40	31.3	26	20.3
Moderately ill	80	62.5	81	63.3	67	52.3	56	43.8	40	31.3	32	25.0
Markedly ill	37	28.9	26	20.3	20	15.6	15	11.7	15	11.7	15	11.7
Severely ill	8	6.3	6	4.7	4	3.1	3	2.3	3	2.3	6	4.7
Total	128	100.0	128	100.0	128	100.0	128	100.0	128	100.0	128	100.0

Table EF15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

	Baseline		Week 1		Week 2		Week 4		Week 6		Week 8/Final	
	n	%	n	%	n	%	n	%	n	%	n	%
Normal, not at all ill			1	0.8	2	1.8	3	2.9	8	9.0	12	10.7
Borderline ill			1	0.8	8	7.1	17	16.2	21	23.6	34	30.4
Mildly ill	3	2.3	11	9.2	25	22.1	31	29.5	33	37.1	22	19.6
Moderately ill	80	62.5	77	64.7	59	52.2	43	41.0	19	21.3	25	22.3
Markedly ill	37	28.9	24	20.2	17	15.0	11	10.5	8	9.0	13	11.6
Severely ill	8	6.3	5	4.2	2	1.8					6	5.4
Total	128	100.0	119	100.0	113	100.0	105	100.0	89	100.0	112	100.0

Table EF16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvement, Open Phase - ITT - LOCF
All Enrolled Patients

Date Produced: January 12, 2001

	Week 1		Week 2		Week 4		Week 6		Week 8/Final	
	n	%	n	%	n	%	n	%	n	%
Very much improved	2	1.7	3	2.5	7	5.8	13	10.8	24	19.0
Much improved	5	4.2	23	19.2	38	31.7	46	38.3	45	35.7
Minimally improved	38	31.9	49	40.8	37	30.8	32	26.7	18	14.3
No change	61	51.3	35	29.2	27	22.5	20	16.7	22	17.5
Minimally worse	12	10.1	9	7.5	10	8.3	7	5.8	11	8.7
Much worse	1	0.8	1	0.8	1	0.8	2	1.7	6	4.8
Total	119	100.0	120	100.0	120	100.0	120	100.0	126	100.0

Table EF17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvement, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

	Week 1		Week 2		Week 4		Week 6		Week 8/Final	
	n	%	n	%	n	%	n	%	n	%
Very much improved	2	1.7	3	2.7	7	6.7	13	14.6	23	20.5
Much improved	5	4.2	23	20.4	38	36.2	40	44.9	40	35.7
Minimally improved	38	31.9	48	42.5	35	33.3	26	29.2	16	14.3
No change	61	51.3	31	27.4	20	19.0	8	9.0	18	16.1
Minimally worse	12	10.1	8	7.1	5	4.8	1	1.1	9	8.0
Much worse	1	0.8					1	1.1	6	5.4
Total	119	100.0	113	100.0	105	100.0	89	100.0	112	100.0

Table EF18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

CGI Efficacy Index by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Mean	0.84	1.12	1.27	1.44	1.54
SD	0.48	0.63	0.74	0.87	1.00
n	119	120	120	120	126
Min	0.33	0.33	0.33	0.33	0.25
Max	3.00	4.00	4.00	4.00	4.00

Table EF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

CGI Efficacy Index: Mean Change from Week One, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 2	Week 4	Week 6	Week 8/Final
Week 1 Mean	0.84	0.84	0.84	0.84
Mean Change	0.28	0.44	0.60	0.76
SD of Change	0.59	0.79	0.90	1.02
n	119	119	119	119
Min	-1.50	-1.00	-1.00	-1.00
Max	2.00	3.50	3.50	3.50
P-value	0.0000	0.0000	0.0000	0.0000

Table EF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

CGI Efficacy Index by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Mean	0.84	1.15	1.35	1.64	1.58
SD	0.48	0.64	0.75	0.89	1.02
n	119	113	105	88	112
Min	0.33	0.33	0.33	0.50	0.25
Max	3.00	4.00	4.00	4.00	4.00

Table EF21

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

CGI Efficacy Index: Mean Change from Week One, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 2	Week 4	Week 6	Week 8/Final
Week 1 Mean	0.86	0.87	0.87	0.84
Mean Change	0.30	0.49	0.76	0.80
SD of Change	0.61	0.81	0.96	1.05
n	112	104	88	105
Min	-1.50	-1.00	-1.00	-1.00
Max	2.00	3.50	3.50	3.50
P-value	0.0000	0.0000	0.0000	0.0000

Table EF22

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions (PGI) by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Mean	5.2	5.3	5.8	5.9	6.1	6.0
SD	1.9	1.7	1.8	2.3	2.0	2.5
n	128	128	128	128	128	128
Min	0	0	1	1	1	0
Max	9	9	9	10	10	10

Table EF23

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions (PGI): Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Baseline mean	5.2	5.2	5.2	5.2	5.2
Mean Change	0.1	0.6	0.7	0.9	0.8
SD of Change	2.2	2.4	2.7	2.6	3.0
n	128	128	128	128	128
Min	-6	-6	-7	-7	-7
Max	7	7	8	8	8
P-value	0.4796	0.0073	0.0068	0.0001	0.0031

Table EF24

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions (PGI) by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Mean	5.2	5.3	5.9	6.2	6.8	6.1
SD	1.9	1.6	1.8	2.2	1.6	2.4
n	128	119	113	104	88	112
Min	0	0	1	1	2	0
Max	9	9	9	10	10	10

Table EF25

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions (PGI): Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Statistics	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Baseline mean	5.2	5.2	5.2	5.2	5.2
Mean Change	0.2	0.7	1.0	1.6	0.9
SD of Change	2.3	2.4	2.7	2.2	2.8
n	119	113	104	88	112
Min	-6	-6	-7	-4	-6
Max	7	7	8	8	8
P-value	0.4798	0.0052	0.0003	0.0000	0.0009

Table EF26

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
1. Apparent Sadness	Mean	3.3	2.9	2.5	2.2	2.0	2.0
	SD	1.0	1.2	1.3	1.4	1.5	1.8
	n	128	128	128	128	128	128
	Min	1	0	0	0	0	0
	Max	5	5	5	5	5	6
2. Reported Sadness	Mean	3.5	3.2	2.7	2.3	2.1	2.0
	SD	1.1	1.3	1.5	1.5	1.5	1.8
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	6	6	6	6	6	6
3. Inner Tension	Mean	2.5	2.4	2.1	1.9	1.8	1.9
	SD	1.3	1.2	1.3	1.4	1.3	1.4

(CONTINUED)

Table EF26

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
3. Inner Tension	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	5	5	5	5	5	6
4. Reduced Sleep	Mean	3.0	3.0	2.7	2.6	2.4	2.2
	SD	1.6	1.5	1.6	1.7	1.8	1.8
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	6	6	6	6	6	6
5. Reduced Appetite	Mean	0.9	1.1	0.8	0.5	0.6	0.6
	SD	1.3	1.4	1.2	1.0	1.2	1.2
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0

(CONTINUED)

Table EF26

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
5. Reduced Appetite	Max	5	5	5	5	6	6
6. Concentration Difficulties	Mean	3.0	2.5	2.3	2.0	1.8	1.7
	SD	1.2	1.3	1.4	1.4	1.4	1.5
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	5	6	5	5	5	5
7. Lassitude	Mean	3.3	2.6	2.2	2.0	1.8	1.8
	SD	1.1	1.4	1.4	1.4	1.5	1.6
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	5	6	5	5	5	5

(CONTINUED)

Table EF26

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
8. Inability to Feel	Mean	3.1	2.6	2.3	2.1	1.7	1.6
	SD	1.3	1.4	1.4	1.5	1.5	1.6
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	6	5	6	5	5	5
9. Pessimistic Thoughts	Mean	2.3	2.0	1.8	1.6	1.5	1.4
	SD	1.2	1.2	1.3	1.3	1.3	1.4
	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	5	5	4	4	4	5
10. Suicidal Thoughts	Mean	1.2	0.9	0.8	0.7	0.6	0.7
	SD	1.1	1.1	1.1	1.0	0.9	1.1

(CONTINUED)

Table EF26

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
10. Suicidal Thoughts	n	128	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	5	4	4	4	4	6
Total Score	Mean	26.2	23.2	20.1	17.9	16.3	15.9
	SD	7.1	8.1	8.9	9.8	10.1	12.0
	n	128	128	128	128	128	128
	Min	8	3	2	0	0	0
	Max	46	46	46	46	46	46

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
1. Apparent Sadness	Baseline mean	3.3	3.3	3.3	3.3	3.3
	Mean Change	-0.4	-0.8	-1.1	-1.3	-1.3
	SD of Change	1.0	1.3	1.4	1.5	1.8
	n	128	128	128	128	128
	Min	-4	-4	-4	-5	-5
	Max	2	2	2	2	4
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
2. Reported Sadness	Baseline mean	3.5	3.5	3.5	3.5	3.5
	Mean Change	-0.3	-0.8	-1.2	-1.5	-1.5
	SD of Change	1.2	1.5	1.5	1.5	1.8
	n	128	128	128	128	128
	Min	-4	-4	-6	-5	-5

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
2. Reported Sadness	Max	4	3	2	2	3
	P-value	0.0019	0.0000	0.0000	0.0000	0.0000
3. Inner Tension	Baseline mean	2.5	2.5	2.5	2.5	2.5
	Mean Change	-0.1	-0.4	-0.5	-0.6	-0.5
	SD of Change	1.1	1.3	1.4	1.5	1.6
	n	128	128	128	128	128
	Min	-4	-4	-4	-4	-4
	Max	3	3	3	3	4
	P-value	0.3696	0.0030	0.0000	0.0000	0.0001
4. Reduced Sleep	Baseline mean	3.0	3.0	3.0	3.0	3.0
	Mean Change	-0.0	-0.3	-0.5	-0.6	-0.8
	SD of Change	1.5	1.7	1.8	1.8	2.0

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
4. Reduced Sleep	n	128	128	128	128	128
	Min	-4	-4	-5	-5	-6
	Max	5	5	4	3	5
	P-value	0.9545	0.0505	0.0046	0.0001	0.0000
5. Reduced Appetite	Baseline mean	0.9	0.9	0.9	0.9	0.9
	Mean Change	0.2	-0.1	-0.3	-0.3	-0.3
	SD of Change	1.2	1.2	1.3	1.2	1.3
	n	128	128	128	128	128
	Min	-3	-4	-4	-4	-4
	Max	3	4	4	4	4
	P-value	0.0307	0.5170	0.0056	0.0193	0.0196
6. Concentration Difficulties	Baseline mean	3.0	3.0	3.0	3.0	3.0

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
6. Concentration Difficulties	Mean Change	-0.5	-0.7	-1.0	-1.2	-1.3
	SD of Change	1.2	1.5	1.6	1.5	1.6
	n	128	128	128	128	128
	Min	-4	-4	-4	-4	-4
	Max	3	3	4	3	3
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
7. Lassitude	Baseline mean	3.3	3.3	3.3	3.3	3.3
	Mean Change	-0.8	-1.1	-1.4	-1.6	-1.6
	SD of Change	1.2	1.4	1.5	1.6	1.7
	n	128	128	128	128	128
	Min	-4	-5	-5	-5	-5
	Max	2	2	2	4	3

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
7. Lassitude	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
8. Inability to Feel	Baseline mean	3.1	3.1	3.1	3.1	3.1
	Mean Change	-0.5	-0.9	-1.1	-1.4	-1.5
	SD of Change	1.2	1.4	1.5	1.5	1.7
	n	128	128	128	128	128
	Min	-5	-5	-5	-5	-5
	Max	4	4	4	2	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
9. Pessimistic Thoughts	Baseline mean	2.3	2.3	2.3	2.3	2.3
	Mean Change	-0.3	-0.5	-0.7	-0.8	-0.9
	SD of Change	0.9	1.2	1.3	1.3	1.6
	n	128	128	128	128	128

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
9. Pessimistic Thoughts	Min	-3	-4	-4	-4	-4
	Max	3	3	3	3	5
	P-value	0.0004	0.0000	0.0000	0.0000	0.0000
10. Suicidal Thoughts	Baseline mean	1.2	1.2	1.2	1.2	1.2
	Mean Change	-0.3	-0.4	-0.5	-0.6	-0.5
	SD of Change	1.0	1.0	1.1	1.0	1.1
	n	128	128	128	128	128
	Min	-3	-3	-4	-4	-4
	Max	3	2	3	1	3
	P-value	0.0018	0.0000	0.0000	0.0000	0.0000
Total Score	Baseline mean	26.2	26.2	26.2	26.2	26.2
	Mean Change	-3.0	-6.0	-8.2	-9.9	-10.2

(CONTINUED)

Table EF27

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
Total Score	SD of Change	6.5	8.1	9.5	9.4	11.6
	n	128	128	128	128	128
	Min	-33	-35	-40	-38	-37
	Max	8	14	14	14	23
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF28

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
1. Apparent Sadness	Mean	3.3	2.8	2.4	1.9	1.6	1.9
	SD	1.0	1.2	1.3	1.4	1.4	1.8
	n	128	118	113	105	89	112
	Min	1	0	0	0	0	0
	Max	5	5	5	5	5	6
2. Reported Sadness	Mean	3.5	3.1	2.6	2.1	1.7	2.0
	SD	1.1	1.2	1.5	1.5	1.4	1.8
	n	128	118	113	105	89	112
	Min	0	0	0	0	0	0
	Max	6	6	5	5	5	6
3. Inner Tension	Mean	2.5	2.4	2.0	1.8	1.6	1.9
	SD	1.3	1.2	1.2	1.3	1.1	1.4

(CONTINUED)

Table EF28

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
3. Inner Tension	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	5	4	4	4	5	6
4. Reduced Sleep	Mean	3.0	3.0	2.7	2.5	2.1	2.1
	SD	1.6	1.5	1.6	1.7	1.6	1.7
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	6	6	6	6	5	6
5. Reduced Appetite	Mean	0.9	1.1	0.8	0.4	0.4	0.6
	SD	1.3	1.3	1.2	0.8	1.0	1.2
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0

(CONTINUED)

Table EF28

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
5. Reduced Appetite	Max	5	4	4	3	6	6
6. Concentration Difficulties	Mean	3.0	2.4	2.2	1.9	1.5	1.6
	SD	1.2	1.3	1.3	1.3	1.3	1.4
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	5	6	5	4	4	5
7. Lassitude	Mean	3.3	2.6	2.1	1.8	1.5	1.8
	SD	1.1	1.4	1.4	1.4	1.3	1.6
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	5	6	4	5	5	5

(CONTINUED)

Table EF28

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
8. Inability to Feel	Mean	3.1	2.6	2.2	1.9	1.3	1.5
	SD	1.3	1.4	1.4	1.4	1.4	1.6
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	6	5	6	5	4	5
9. Pessimistic Thoughts	Mean	2.3	2.0	1.7	1.5	1.3	1.4
	SD	1.2	1.2	1.2	1.3	1.2	1.4
	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	5	5	4	4	4	5
10. Suicidal Thoughts	Mean	1.2	0.9	0.7	0.6	0.4	0.7
	SD	1.1	1.1	1.1	1.0	0.8	1.2

(CONTINUED)

Table EF28

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8 /Final
10. Suicidal Thoughts	n	128	119	113	105	89	112
	Min	0	0	0	0	0	0
	Max	5	4	4	4	4	6
Total Score	Mean	26.2	23.2	19.5	16.3	13.3	15.4
	SD	7.1	8.0	8.5	9.1	9.0	12.1
	n	128	118	113	105	89	112
	Min	8	3	2	0	0	0
	Max	46	41	38	37	42	46

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
1. Apparent Sadness	Baseline mean	3.3	3.3	3.2	3.2	3.2
	Mean Change	-0.4	-0.9	-1.3	-1.6	-1.3
	SD of Change	1.1	1.3	1.4	1.5	1.8
	n	118	113	105	89	112
	Min	-4	-4	-4	-5	-4
	Max	2	2	2	2	4
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
2. Reported Sadness	Baseline mean	3.5	3.5	3.5	3.4	3.5
	Mean Change	-0.4	-0.9	-1.4	-1.8	-1.5
	SD of Change	1.3	1.5	1.5	1.5	1.9
	n	118	113	105	89	112
	Min	-4	-4	-6	-5	-5

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
2. Reported Sadness	Max	4	3	1	2	3
	P-value	0.0019	0.0000	0.0000	0.0000	0.0000
3. Inner Tension	Baseline mean	2.5	2.5	2.4	2.4	2.4
	Mean Change	-0.1	-0.4	-0.6	-0.9	-0.5
	SD of Change	1.1	1.3	1.5	1.6	1.6
	n	119	113	105	89	112
	Min	-4	-4	-4	-4	-4
	Max	3	3	3	3	4
	P-value	0.3697	0.0014	0.0000	0.0000	0.0014
4. Reduced Sleep	Baseline mean	3.1	3.0	3.0	3.1	3.0
	Mean Change	-0.0	-0.3	-0.6	-1.0	-0.9
	SD of Change	1.6	1.8	1.9	1.8	2.0

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
4. Reduced Sleep	n	119	113	105	89	112
	Min	-4	-4	-5	-5	-6
	Max	5	5	4	3	5
	P-value	0.9545	0.0850	0.0031	0.0000	0.0000
5. Reduced Appetite	Baseline mean	0.9	0.8	0.8	0.8	0.8
	Mean Change	0.3	-0.1	-0.4	-0.3	-0.2
	SD of Change	1.3	1.3	1.3	1.2	1.3
	n	119	113	105	89	112
	Min	-3	-4	-4	-4	-3
	Max	3	4	3	2	4
	P-value	0.0306	0.4659	0.0011	0.0057	0.1051
6. Concentration Difficulties	Baseline mean	3.0	2.9	3.0	2.9	3.0

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
6. Concentration Difficulties	Mean Change	-0.6	-0.8	-1.1	-1.5	-1.4
	SD of Change	1.3	1.5	1.6	1.4	1.6
	n	119	113	105	89	112
	Min	-4	-4	-4	-4	-4
	Max	3	3	4	3	3
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
7. Lassitude	Baseline mean	3.4	3.4	3.4	3.5	3.4
	Mean Change	-0.8	-1.3	-1.6	-2.0	-1.6
	SD of Change	1.3	1.4	1.5	1.5	1.7
	n	119	113	105	89	112
	Min	-4	-5	-5	-5	-5
	Max	2	2	1	4	3

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
7. Lassitude	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
8. Inability to Feel	Baseline mean	3.2	3.1	3.1	3.2	3.1
	Mean Change	-0.5	-1.0	-1.2	-1.9	-1.6
	SD of Change	1.3	1.4	1.5	1.4	1.7
	n	119	113	105	89	112
	Min	-5	-5	-5	-5	-5
	Max	4	4	4	1	2
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
9. Pessimistic Thoughts	Baseline mean	2.4	2.3	2.3	2.3	2.3
	Mean Change	-0.3	-0.6	-0.9	-1.1	-0.9
	SD of Change	0.9	1.2	1.3	1.4	1.6
	n	119	113	105	89	112

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
9. Pessimistic Thoughts	Min	-3	-4	-4	-4	-4
	Max	3	3	2	2	5
	P-value	0.0004	0.0000	0.0000	0.0000	0.0000
10. Suicidal Thoughts	Baseline mean	1.2	1.2	1.2	1.2	1.2
	Mean Change	-0.3	-0.5	-0.6	-0.7	-0.5
	SD of Change	1.0	1.0	1.1	1.0	1.1
	n	119	113	105	89	112
	Min	-3	-3	-4	-4	-4
	Max	3	2	3	1	3
	P-value	0.0018	0.0000	0.0000	0.0000	0.0000
Total Score	Baseline mean	26.2	26.1	26.1	26.1	25.8
	Mean Change	-3.0	-6.6	-9.8	-12.8	-10.4

(CONTINUED)

Table EF29

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

MADRS Items: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

MADRS		Week 1	Week 2	Week 4	Week 6	Week 8 /Final
Total Score	SD of Change	6.5	8.4	9.4	8.7	11.7
	n	118	113	105	89	112
	Min	-33	-35	-40	-38	-37
	Max	8	14	10	6	23
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000

Table EF30

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Score by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anxiety	Mean	13.8	12.3	11.5	10.6	9.7	9.6
	SD	5.3	5.9	6.4	6.6	6.4	6.8
	n	124	128	128	128	128	128
	Min	1	0	0	0	0	0
	Max	23	23	23	23	23	23
Depression	Mean	16.3	13.2	12.2	11.6	10.6	10.6
	SD	4.9	6.3	6.9	7.3	7.5	7.7
	n	125	128	128	128	128	128
	Min	2	0	0	0	0	0
	Max	23	23	23	23	23	23
Somatic	Mean	11.1	11.1	10.5	10.0	9.7	10.1
	SD	5.1	5.3	5.5	5.7	5.6	5.8

(CONTINUED)

Table EF30

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Score by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Somatic	n	127	128	128	128	128	128
	Min	1	0	0	0	0	0
	Max	23	21	22	23	23	23
Anger-hostility	Mean	10.8	8.9	9.0	9.2	9.0	8.6
	SD	6.1	6.1	6.4	6.9	6.5	6.9
	n	125	128	128	128	128	128
	Min	0	0	0	0	0	0
	Max	23	23	23	23	23	23

Table EF31

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anxiety	Baseline mean	13.8	13.8	13.8	13.8	13.8
	Mean Change	-1.6	-2.4	-3.3	-4.2	-4.3
	SD of Change	4.4	5.8	6.2	6.3	7.0
	n	124	124	124	124	124
	Min	-21	-21	-23	-23	-23
	Max	7	15	11	11	11
	P-value	0.0001	0.0000	0.0000	0.0000	0.0000
Depression	Baseline mean	16.3	16.3	16.3	16.3	16.3
	Mean Change	-3.2	-4.2	-4.7	-5.6	-5.7
	SD of Change	5.6	6.5	7.0	7.1	7.5
	n	125	125	125	125	125
	Min	-22	-22	-23	-22	-22

(CONTINUED)

Table EF31

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Depression	Max	7	8	11	7	13
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
Somatic	Baseline mean	11.1	11.1	11.1	11.1	11.1
	Mean Change	0.1	-0.7	-1.1	-1.4	-0.9
	SD of Change	4.2	4.5	4.5	4.4	5.2
	n	127	127	127	127	127
	Min	-16	-14	-16	-14	-14
	Max	13	12	11	11	13
	P-value	0.7657	0.1044	0.0089	0.0006	0.0542
Anger-hostility	Baseline mean	10.8	10.8	10.8	10.8	10.8
	Mean Change	-1.8	-1.7	-1.5	-1.7	-2.0
	SD of Change	5.0	6.2	6.8	6.8	7.1

(CONTINUED)

Table EF31

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscale: Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anger-hostility	n	125	125	125	125	125
	Min	-15	-18	-19	-17	-19
	Max	12	12	19	15	14
	P-value	0.0001	0.0032	0.0137	0.0055	0.0016

Table EF32

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anxiety	Mean	13.8	12.1	10.8	9.5	8.1	9.4
	SD	5.3	6.0	6.3	6.3	6.1	7.0
	n	124	118	110	103	88	107
	Min	1	0	0	0	0	0
	Max	23	23	23	23	22	23
Depression	Mean	16.3	13.0	11.8	10.5	8.8	10.5
	SD	4.9	6.4	7.0	7.3	7.3	8.0
	n	125	117	112	101	88	105
	Min	2	0	0	0	0	0
	Max	23	23	23	23	23	23
Somatic	Mean	11.1	10.9	10.0	9.5	8.2	9.8
	SD	5.1	5.2	5.5	5.6	4.9	5.6

(CONTINUED)

Table EF32

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Score by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Baseline	Week 1	Week 2	Week 4	Week 6	Week 8/Final
Somatic	n	127	118	109	103	89	107
	Min	1	0	0	0	0	0
	Max	23	21	22	23	23	23
Anger-hostility	Mean	10.8	8.7	8.5	8.3	7.8	8.3
	SD	6.1	6.0	6.4	6.8	6.2	6.8
	n	125	118	112	104	89	107
	Min	0	0	0	0	0	0
	Max	23	23	23	23	23	23

Table EF33

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anxiety	Baseline mean	13.7	13.5	13.6	13.9	13.9
	Mean Change	-1.8	-2.8	-4.2	-5.9	-4.5
	SD of Change	4.5	6.1	6.4	6.3	6.9
	n	114	106	99	86	106
	Min	-21	-21	-23	-23	-21
	Max	7	15	6	6	11
	P-value	0.0001	0.0000	0.0000	0.0000	0.0000
Depression	Baseline mean	16.4	16.3	16.4	16.3	16.3
	Mean Change	-3.5	-4.6	-5.9	-7.5	-5.9
	SD of Change	5.8	6.6	7.2	7.0	7.6
	n	114	109	98	86	103
	Min	-22	-22	-23	-22	-22

(CONTINUED)

Table EF33

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Depression	Max	7	8	11	4	13
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000
Somatic	Baseline mean	10.9	10.9	11.1	10.4	10.9
	Mean Change	0.1	-0.9	-1.6	-2.1	-1.1
	SD of Change	4.3	4.7	4.5	4.3	5.2
	n	117	108	102	88	106
	Min	-16	-14	-16	-14	-14
	Max	13	12	8	8	13
	P-value	0.7658	0.0494	0.0005	0.0000	0.0378
Anger-hostility	Baseline mean	10.7	10.4	10.3	10.4	10.5
	Mean Change	-1.9	-1.8	-2.0	-2.6	-2.1
	SD of Change	5.2	6.5	7.2	7.1	7.2

(CONTINUED)

Table EF33

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

KSQ Subscales: Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

KSQ Subscales		Week 1	Week 2	Week 4	Week 6	Week 8/Final
Anger-hostility	n	115	109	102	87	106
	Min	-15	-18	-19	-17	-19
	Max	12	12	19	15	14
	P-value	0.0001	0.0053	0.0064	0.0013	0.0030

Table EF34

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Rush Sexual Inventory: Patients' Condition at Baseline
All Enrolled Patients

Date Produced: January 12, 2001

		Reboxetine (N=128)	
		n	%
Sexual dysfunction on medication?	Yes	64	50.0
	No	64	50.0
You/partner using birth control?	Yes	52	40.6
	No	31	24.2
	Not Applicable	45	35.2
Ever has surgical/medical procedures on reproductive organs?	Yes	49	38.3
	No	79	61.7
Ever has any non-routine investigation of reproductive organ?	Yes	20	15.6
	No	108	84.4
Ever been investigated for sexual dysfunction?	Yes	5	3.9
	No	123	96.1

(CONTINUED)

Table EF34

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Rush Sexual Inventory: Patients' Condition at Baseline

All Enrolled Patients

Date Produced: January 12, 2001

		Reboxetine (N=128)	
		n	%
Ever received treatment for sexual dysfunction?	Yes	5	3.9
	No	123	96.1

Table EF35

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Frequency of Pleasurable Thoughts	Mean	32.1	37.2	40.7
	SD	30.1	29.8	29.7
	n	127	128	128
	Min	0	0	0
	Max	97	100	98
Ability to Become Sexually Excited	Mean	35.6	43.4	46.4
	SD	29.7	32.1	31.0
	n	126	127	128
	Min	0	0	0
	Max	98	100	98
Frequency of Desires to Inititate Sexual Activity	Mean	26.6	34.7	38.2
	SD	29.5	31.7	31.8

(CONTINUED)

Table EF35

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Frequency of Desires to Inititate Sexual Activity	n	126	127	128
	Min	0	0	0
	Max	100	100	100
Frequency of Initiating Sexual Activity	Mean	18.0	24.5	27.6
	SD	23.9	29.0	28.4
	n	126	127	128
	Min	0	0	0
	Max	95	98	98
Overall Degree of Sexual Satisfaction Attained	Mean	26.9	34.6	39.8
	SD	28.5	32.4	32.8
	n	126	127	128
	Min	0	0	0

(CONTINUED)

Table EF35

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Overall Degree of Sexual Satisfaction Attained	Max	96	99	97

Table EF36

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Frequency of Pleasurable Thoughts	Baseline mean	32.1	32.1
	Mean Change	5.4	8.9
	SD of Change	23.4	29.7
	n	127	127
	Min	-75	-73
	Max	81	83
	P-value	0.0102	0.0010
Ability to Become Sexually Excited	Baseline mean	35.6	35.6
	Mean Change	8.1	10.9
	SD of Change	24.2	28.1
	n	126	126
	Min	-50	-70

(CONTINUED)

Table EF36

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Ability to Become Sexually Excited	Max	82	79
	P-value	0.0003	0.0000
Frequency of Desires to Inititate Sexual Activity	Baseline mean	26.6	26.6
	Mean Change	8.4	12.3
	SD of Change	25.6	29.6
	n	126	126
	Min	-57	-70
	Max	84	82
	P-value	0.0004	0.0000
Frequency of Initiating Sexual Activity	Baseline mean	18.0	18.0
	Mean Change	6.7	10.1
	SD of Change	23.0	25.2

(CONTINUED)

Table EF36

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Frequency of Initiating Sexual Activity	n	126	126
	Min	-57	-79
	Max	93	93
	P-value	0.0013	0.0000
Overall Degree of Sexual Satisfaction Attained	Baseline mean	26.9	26.9
	Mean Change	8.0	12.9
	SD of Change	27.5	29.4
	n	126	126
	Min	-74	-72
	Max	93	86
	P-value	0.0014	0.0000

Table EF37

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Frequency of Pleasurable Thoughts	Mean	32.1	38.2	40.2
	SD	30.1	28.8	28.7
	n	127	104	113
	Min	0.0	0.0	0.0
	Max	97.0	100.0	97.0
Ability to Become Sexually Excited	Mean	35.6	43.5	46.4
	SD	29.7	31.8	30.7
	n	126	104	113
	Min	0.0	0.0	0.0
	Max	98.0	100.0	97.0
Frequency of Desires to Inititate Sexual Activity	Mean	26.6	35.7	37.3
	SD	29.5	31.3	30.8

(CONTINUED)

Table EF37

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Frequency of Desires to Inititate Sexual Activity	n	126	104	113
	Min	0.0	0.0	0.0
	Max	100.0	100.0	95.0
Frequency of Initiating Sexual Activity	Mean	18.0	24.3	26.0
	SD	23.9	28.4	26.8
	n	126	103	111
	Min	0.0	0.0	0.0
	Max	95.0	98.0	95.0
Overall Degree of Sexual Satisfaction Attained	Mean	26.9	36.2	40.3
	SD	28.5	32.9	33.3
	n	126	102	111
	Min	0.0	0.0	0.0

(CONTINUED)

Table EF37

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Baseline	Week 4	Week 8/Final Visit
Overall Degree of Sexual Satisfaction Attained	Max	96.0	99.0	97.0

Table EF38

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Frequency of Pleasurable Thoughts	Baseline mean	31.9	32.2
	Mean Change	6.7	8.3
	SD of Change	25.9	30.5
	n	103	112
	Min	-75	-73
	Max	81	83
	P-value	0.0101	0.0049
Ability to Become Sexually Excited	Baseline mean	34.0	36.0
	Mean Change	9.9	10.5
	SD of Change	26.4	28.1
	n	103	111
	Min	-50	-70

(CONTINUED)

Table EF38

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Ability to Become Sexually Excited	Max	82	79
	P-value	0.0002	0.0002
Frequency of Desires to Inititate Sexual Activity	Baseline mean	25.8	26.4
	Mean Change	10.2	11.5
	SD of Change	28.0	30.0
	n	103	111
	Min	-57	-70
	Max	84	79
	P-value	0.0003	0.0001
Frequency of Initiating Sexual Activity	Baseline mean	16.3	17.3
	Mean Change	8.3	9.2
	SD of Change	25.3	24.8

(CONTINUED)

Table EF38

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Mean Change from Baseline, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Variable	Statistics	Week 4	Week 8/Final Visit
Frequency of Initiating Sexual Activity	n	102	109
	Min	-57	-79
	Max	93	77
	P-value	0.0013	0.0002
Overall Degree of Sexual Satisfaction Attained	Baseline mean	26.6	26.4
	Mean Change	10.0	13.9
	SD of Change	30.4	28.4
	n	101	109
	Min	-74	-72
	Max	93	86
	P-value	0.0013	0.0000

Table EF39

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
Masturbation	Never	75	59.1	70	54.7	69	53.9
	Once a Week	36	28.3	32	25.0	28	21.9
	2-4 Times Per Week	15	11.8	23	18.0	28	21.9
	5-10 Times Per Week	1	0.8	3	2.3	3	2.3
	Total	127	100.0	128	100.0	128	100.0
Intercourse	Never	74	58.7	75	59.1	73	57.5
	Once a Week	44	34.9	39	30.7	34	26.8
	2-4 Times Per Week	7	5.6	11	8.7	18	14.2
	5-10 Times Per Week	1	0.8	2	1.6	2	1.6
	Total	126	100.0	127	100.0	127	100.0
Oral Sex	Never	95	75.4	93	73.2	93	73.2

(CONTINUED)

Table EF39

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
Oral Sex	Once a Week	21	16.7	24	18.9	23	18.1
	2-4 Times Per Week	8	6.3	8	6.3	11	8.7
	5-10 Times Per Week	2	1.6	2	1.6		
	Total	126	100.0	127	100.0	127	100.0

Table EF40

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
Masturbation	Never	75	59.1	57	54.8	58	52.3
	Once a Week	36	28.3	27	26.0	24	21.6
	2-4 Times Per Week	15	11.8	17	16.3	26	23.4
	5-10 Times Per Week	1	0.8	3	2.9	3	2.7
	Total	127	100.0	104	100.0	111	100.0
Intercourse	Never	74	58.7	61	58.7	65	58.0
	Once a Week	44	34.9	34	32.7	30	26.8
	2-4 Times Per Week	7	5.6	8	7.7	15	13.4
	5-10 Times Per Week	1	0.8	1	1.0	2	1.8
	Total	126	100.0	104	100.0	112	100.0
Oral Sex	Never	95	75.4	77	74.0	81	72.3

(CONTINUED)

Table EF40

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
Oral Sex	Once a Week	21	16.7	21	20.2	22	19.6
	2-4 Times Per Week	8	6.3	5	4.8	9	8.0
	5-10 Times Per Week	2	1.6	1	1.0		
	Total	126	100.0	104	100.0	112	100.0

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
1. Spontaneous daytime erections	Yes	8	19.5	6	14.6	7	17.1
	No	33	80.5	35	85.4	34	82.9
	Total	41	100.0	41	100.0	41	100.0
2. Painful erections	Yes	1	2.4	5	12.2	1	2.4
	No	40	97.6	36	87.8	40	97.6
	Total	41	100.0	41	100.0	41	100.0
3. Erection when sexually aroused	Yes	30	73.2	31	75.6	33	80.5
	No	11	26.8	10	24.4	8	19.5
	Total	41	100.0	41	100.0	41	100.0
4. Difficulty getting an erection when sexually stimulated	Yes	17	41.5	12	29.3	12	29.3
	No	24	58.5	29	70.7	29	70.7

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
4. Difficulty getting an erection when sexually stimulated	Total	41	100.0	41	100.0	41	100.0
5. Difficulty maintaining an erection to complete sexual act	Yes	16	39.0	18	43.9	14	34.1
	No	25	61.0	23	56.1	27	65.9
	Total	41	100.0	41	100.0	41	100.0
6. Waking up from sleep with an erection	Yes	20	48.8	18	43.9	21	51.2
	No	21	51.2	23	56.1	20	48.8
	Total	41	100.0	41	100.0	41	100.0
7. Requiring more stimuli than usual to achieve an erection	Yes	22	53.7	20	48.8	18	43.9
	No	19	46.3	21	51.2	23	56.1
	Total	41	100.0	41	100.0	41	100.0

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
8. Requiring more stimuli than usual to maintain an erection	Yes	19	46.3	16	39.0	16	39.0
	No	22	53.7	25	61.0	25	61.0
	Total	41	100.0	41	100.0	41	100.0
9. Decreased fullness of erection	Yes	20	48.8	21	51.2	17	41.5
	No	21	51.2	20	48.8	24	58.5
	Total	41	100.0	41	100.0	41	100.0
10. Increased sensitivity of genitals upon physical stimulation	Yes	6	14.6	9	22.0	6	14.6
	No	35	85.4	32	78.0	35	85.4
	Total	41	100.0	41	100.0	41	100.0
11. Decreased sensitivity of genitals upon physical stimulation	Yes	11	26.8	11	26.8	11	26.8
	No	30	73.2	30	73.2	30	73.2

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
11. Decreased sensitivity of genitals upon physical stimulation	Total	41	100.0	41	100.0	41	100.0
12. Orgasm	Yes	30	75.0	28	68.3	30	73.2
	No	10	25.0	13	31.7	11	26.8
	Total	40	100.0	41	100.0	41	100.0
13. Ejaculation	Yes	31	75.6	28	68.3	30	73.2
	No	10	24.4	13	31.7	11	26.8
	Total	41	100.0	41	100.0	41	100.0
14. Painful orgasm/ejaculation	Yes	3	7.3	7	17.1	8	19.5
	No	38	92.7	34	82.9	33	80.5
	Total	41	100.0	41	100.0	41	100.0

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
15. Orgasm without ejaculation	Yes	2	5.0			4	10.0
	No	38	95.0	40	100.0	36	90.0
	Total	40	100.0	40	100.0	40	100.0
16. Delay in achieving orgasm/ejaculation but eventually doing so	Yes	20	48.8	13	31.7	10	24.4
	No	21	51.2	28	68.3	31	75.6
	Total	41	100.0	41	100.0	41	100.0
17. Inability to achieve orgasm/ejaculation	Yes	9	22.0	10	24.4	9	22.0
	No	32	78.0	31	75.6	32	78.0
	Total	41	100.0	41	100.0	41	100.0
18. Orgasm without erection	Yes	1	2.5	5	12.2	7	17.1
	No	39	97.5	36	87.8	34	82.9

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
18. Orgasm without erection	Total	40	100.0	41	100.0	41	100.0
19. Orgasm occurring during sleep	Yes	2	5.0	3	7.3	1	2.4
	No	38	95.0	38	92.7	40	97.6
	Total	40	100.0	41	100.0	41	100.0
20. Genital pain during sexual contact	Yes	2	4.9	4	9.8	1	2.4
	No	39	95.1	37	90.2	40	97.6
	Total	41	100.0	41	100.0	41	100.0
21. Orgasm/ejaculation occurring earlier than desired	Yes	8	19.5	12	29.3	14	34.1
	No	33	80.5	29	70.7	27	65.9
	Total	41	100.0	41	100.0	41	100.0

(CONTINUED)

Table EF41

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
22. Experiencing orgasm without sexual provocation (spontaneously, except in sleep)	No	41	100.0	41	100.0	41	100.0
	Total	41	100.0	41	100.0	41	100.0
23. Generally decreased intensity of orgasm	Yes	19	46.3	18	43.9	14	34.1
	No	22	53.7	23	56.1	27	65.9
	Total	41	100.0	41	100.0	41	100.0

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
1. Spontaneous daytime erections	Yes	8	19.5	5	14.7	6	18.2
	No	33	80.5	29	85.3	27	81.8
	Total	41	100.0	34	100.0	33	100.0
2. Painful erections	Yes	1	2.4	4	11.8		
	No	40	97.6	30	88.2	33	100.0
	Total	41	100.0	34	100.0	33	100.0
3. Erection when sexually aroused	Yes	30	73.2	25	73.5	27	81.8
	No	11	26.8	9	26.5	6	18.2
	Total	41	100.0	34	100.0	33	100.0
4. Difficulty getting an erection when sexually stimulated	Yes	17	41.5	9	26.5	9	27.3
	No	24	58.5	25	73.5	24	72.7

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
4. Difficulty getting an erection when sexually stimulated	Total	41	100.0	34	100.0	33	100.0
5. Difficulty maintaining an erection to complete sexual act	Yes	16	39.0	14	41.2	11	33.3
	No	25	61.0	20	58.8	22	66.7
	Total	41	100.0	34	100.0	33	100.0
6. Waking up from sleep with an erection	Yes	20	48.8	15	44.1	16	48.5
	No	21	51.2	19	55.9	17	51.5
	Total	41	100.0	34	100.0	33	100.0
7. Requiring more stimuli than usual to achieve an erection	Yes	22	53.7	16	47.1	15	45.5
	No	19	46.3	18	52.9	18	54.5
	Total	41	100.0	34	100.0	33	100.0

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
8. Requiring more stimuli than usual to maintain an erection	Yes	19	46.3	13	39.4	13	39.4
	No	22	53.7	20	60.6	20	60.6
	Total	41	100.0	33	100.0	33	100.0
9. Decreased fullness of erection	Yes	20	48.8	17	51.5	14	42.4
	No	21	51.2	16	48.5	19	57.6
	Total	41	100.0	33	100.0	33	100.0
10. Increased sensitivity of genitals upon physical stimulation	Yes	6	14.6	6	18.2	3	9.1
	No	35	85.4	27	81.8	30	90.9
	Total	41	100.0	33	100.0	33	100.0
11. Decreased sensitivity of genitals upon physical stimulation	Yes	11	26.8	7	21.2	8	24.2
	No	30	73.2	26	78.8	25	75.8

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
11. Decreased sensitivity of genitals upon physical stimulation	Total	41	100.0	33	100.0	33	100.0
12. Orgasm	Yes	30	75.0	23	69.7	25	75.8
	No	10	25.0	10	30.3	8	24.2
	Total	40	100.0	33	100.0	33	100.0
13. Ejaculation	Yes	31	75.6	23	69.7	26	78.8
	No	10	24.4	10	30.3	7	21.2
	Total	41	100.0	33	100.0	33	100.0
14. Painful orgasm/ejaculation	Yes	3	7.3	6	18.2	7	21.2
	No	38	92.7	27	81.8	26	78.8
	Total	41	100.0	33	100.0	33	100.0

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
15. Orgasm without ejaculation	Yes	2	5.0			4	12.5
	No	38	95.0	31	100.0	28	87.5
	Total	40	100.0	31	100.0	32	100.0
16. Delay in achieving orgasm/ejaculation but eventually doing so	Yes	20	48.8	8	25.0	8	24.2
	No	21	51.2	24	75.0	25	75.8
	Total	41	100.0	32	100.0	33	100.0
17. Inability to achieve orgasm/ejaculation	Yes	9	22.0	7	21.9	8	24.2
	No	32	78.0	25	78.1	25	75.8
	Total	41	100.0	32	100.0	33	100.0
18. Orgasm without erection	Yes	1	2.5	4	12.5	7	21.9
	No	39	97.5	28	87.5	25	78.1

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
18. Orgasm without erection	Total	40	100.0	32	100.0	32	100.0
19. Orgasm occurring during sleep	Yes	2	5.0	2	6.3		
	No	38	95.0	30	93.8	33	100.0
	Total	40	100.0	32	100.0	33	100.0
20. Genital pain during sexual contact	Yes	2	4.9	3	9.4		
	No	39	95.1	29	90.6	33	100.0
	Total	41	100.0	32	100.0	33	100.0
21. Orgasm/ejaculation occurring earlier than desired	Yes	8	19.5	10	31.3	10	31.3
	No	33	80.5	22	68.8	22	68.8
	Total	41	100.0	32	100.0	32	100.0

(CONTINUED)

Table EF42

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
22. Experiencing orgasm without sexual provocation (spontaneously, except in sleep)	No	41	100.0	32	100.0	32	100.0
	Total	41	100.0	32	100.0	32	100.0
23. Generally decreased intensity of orgasm	Yes	19	46.3	13	40.6	10	30.3
	No	22	53.7	19	59.4	23	69.7
	Total	41	100.0	32	100.0	33	100.0

Table EF43

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
1. Increased sensitivity, other than pain, in breasts upon physical contact	Yes	14	16.3	16	18.4	17	19.5
	No	72	83.7	71	81.6	70	80.5
	Total	86	100.0	87	100.0	87	100.0
2. Increased sensitivity of genitals, other than pain, upon physical contact	Yes	7	8.1	20	23.0	15	17.2
	No	79	91.9	67	77.0	72	82.8
	Total	86	100.0	87	100.0	87	100.0
3. Pain in breasts upon physical contact	Yes	8	9.3	6	6.9	6	6.9
	No	78	90.7	81	93.1	81	93.1
	Total	86	100.0	87	100.0	87	100.0
4. Pain in genitals upon physical contact	Yes	3	3.5	4	4.6		
	No	83	96.5	83	95.4	87	100.0

(CONTINUED)

Table EF43

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
4. Pain in genitals upon physical contact	Total	86	100.0	87	100.0	87	100.0
5. Decreased sensitivity in breasts upon physical contact	Yes	16	18.6	8	9.2	5	5.7
	No	70	81.4	79	90.8	82	94.3
	Total	86	100.0	87	100.0	87	100.0
6. Decreased sensitivity in genitals upon physical contact	Yes	18	20.9	11	12.6	6	6.9
	No	68	79.1	76	87.4	81	93.1
	Total	86	100.0	87	100.0	87	100.0
7. Inadequate swelling or vaginal lubrication during sexual contact	Yes	24	27.9	20	23.0	12	13.8
	No	62	72.1	67	77.0	75	86.2
	Total	86	100.0	87	100.0	87	100.0
8. Orgasm	Yes	33	38.4	40	46.0	50	57.5

(CONTINUED)

Table EF43

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
8. Orgasm	No	53	61.6	47	54.0	37	42.5
	Total	86	100.0	87	100.0	87	100.0
9. Multiple orgasm	Yes	8	9.3	14	16.1	17	19.5
	No	78	90.7	73	83.9	70	80.5
	Total	86	100.0	87	100.0	87	100.0
10. Difficulty achieving orgasm, but eventually being able to	Yes	28	33.3	23	26.4	22	25.3
	No	56	66.7	64	73.6	65	74.7
	Total	84	100.0	87	100.0	87	100.0
11. Inability to achieve orgasm	Yes	21	25.0	21	24.1	11	12.6
	No	63	75.0	66	75.9	76	87.4
	Total	84	100.0	87	100.0	87	100.0

(CONTINUED)

Table EF43

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
12. Experiencing orgasm without sexual provocation (spontaneously)	Yes	3	3.5	5	5.7	9	10.3
	No	83	96.5	82	94.3	78	89.7
	Total	86	100.0	87	100.0	87	100.0
13. Painful orgasm	Yes					1	1.1
	No	85	100.0	87	100.0	86	98.9
	Total	85	100.0	87	100.0	87	100.0
14. Decreased intensity or orgasm	Yes	26	31.0	13	14.9	11	12.6
	No	58	69.0	74	85.1	76	87.4
	Total	84	100.0	87	100.0	87	100.0
15. Involuntary vaginal contractions that prevent vaginal penetration	Yes	3	3.5	1	1.1	2	2.3
	No	82	96.5	86	98.9	85	97.7

(CONTINUED)

Table EF43

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
15. Involuntary vaginal contractions that prevent vaginal penetration	Total	85	100.0	87	100.0	87	100.0
16. Physical pain during sexual activity	Yes	5	6.0	4	4.6	3	3.4
	No	79	94.0	83	95.4	84	96.6
	Total	84	100.0	87	100.0	87	100.0

Table EF44

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
1. Increased sensitivity, other than pain, in breasts upon physical contact	Yes	14	16.3	12	17.6	16	20.3
	No	72	83.7	56	82.4	63	79.7
	Total	86	100.0	68	100.0	79	100.0
2. Increased sensitivity of genitals, other than pain, upon physical contact	Yes	7	8.1	18	26.5	13	16.5
	No	79	91.9	50	73.5	66	83.5
	Total	86	100.0	68	100.0	79	100.0
3. Pain in breasts upon physical contact	Yes	8	9.3	4	5.9	5	6.3
	No	78	90.7	64	94.1	74	93.7
	Total	86	100.0	68	100.0	79	100.0
4. Pain in genitals upon physical contact	Yes	3	3.5	4	6.0		
	No	83	96.5	63	94.0	79	100.0

(CONTINUED)

Table EF44

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
4. Pain in genitals upon physical contact	Total	86	100.0	67	100.0	79	100.0
5. Decreased sensitivity in breasts upon physical contact	Yes	16	18.6	5	7.4	2	2.5
	No	70	81.4	63	92.6	77	97.5
	Total	86	100.0	68	100.0	79	100.0
6. Decreased sensitivity in genitals upon physical contact	Yes	18	20.9	8	11.8	4	5.1
	No	68	79.1	60	88.2	75	94.9
	Total	86	100.0	68	100.0	79	100.0
7. Inadequate swelling or vaginal lubrication during sexual contact	Yes	24	27.9	15	22.1	9	11.4
	No	62	72.1	53	77.9	70	88.6
	Total	86	100.0	68	100.0	79	100.0
8. Orgasm	Yes	33	38.4	30	44.1	46	59.0

(CONTINUED)

Table EF44

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
8. Orgasm	No	53	61.6	38	55.9	32	41.0
	Total	86	100.0	68	100.0	78	100.0
9. Multiple orgasm	Yes	8	9.3	9	13.2	17	21.8
	No	78	90.7	59	86.8	61	78.2
	Total	86	100.0	68	100.0	78	100.0
10. Difficulty achieving orgasm, but eventually being able to	Yes	28	33.3	16	23.9	18	23.4
	No	56	66.7	51	76.1	59	76.6
	Total	84	100.0	67	100.0	77	100.0
11. Inability to achieve orgasm	Yes	21	25.0	16	23.9	8	10.3
	No	63	75.0	51	76.1	70	89.7
	Total	84	100.0	67	100.0	78	100.0

(CONTINUED)

Table EF44

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
12. Experiencing orgasm without sexual provocation (spontaneously)	Yes	3	3.5	4	6.0	9	11.5
	No	83	96.5	63	94.0	69	88.5
	Total	86	100.0	67	100.0	78	100.0
13. Painful orgasm	Yes					1	1.3
	No	85	100.0	67	100.0	77	98.7
	Total	85	100.0	67	100.0	78	100.0
14. Decreased intensity or orgasm	Yes	26	31.0	7	10.4	9	11.5
	No	58	69.0	60	89.6	69	88.5
	Total	84	100.0	67	100.0	78	100.0
15. Involuntary vaginal contractions that prevent vaginal penetration	Yes	3	3.5	1	1.5	2	2.6
	No	82	96.5	66	98.5	76	97.4

(CONTINUED)

Table EF44

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Open Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Baseline		Week 4		Week 8/ Final Visit	
		n	%	n	%	n	%
15. Involuntary vaginal contractions that prevent vaginal penetration	Total	85	100.0	67	100.0	78	100.0
16. Physical pain during sexual activity	Yes	5	6.0	4	6.0	3	3.9
	No	79	94.0	63	94.0	74	96.1
	Total	84	100.0	67	100.0	77	100.0

Table EF45

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Response Rate by Visit, Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

HAMD Versions	Week 1		Week 2		Week 3		Week 4		Week 5		Week 6		Week 7		Week 8	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HAMD-25	6	4.7	23	18.0	37	28.9	38	29.7	44	34.4	53	41.4	57	44.5	67	52.3
HAMD-17	6	4.7	22	17.2	30	23.4	34	26.6	39	30.5	40	31.3	49	38.3	58	45.3
HAMD-28	7	5.5	27	21.1	36	28.1	36	28.1	45	35.2	46	35.9	53	41.4	56	43.8

Note: 1. Response is defined as >= 50% reduction in HAMD total score since baseline.
2. Percentages are calculated based on the total number of enrolled patients (128 patients).
3. No. of responders who completed 8 weeks of treatment = 58.

Table EF46

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reasons of Discontinuation of Drop-out Patients Who Were Classified as Responders (50% Reduction of HAMD-25), Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Termination Day	Reason of Discontinuation	Comment	Additional Comment
Fava	51114	54/Female	37	Protocol violation	PATIENT HAD A POSITIVE DRUG SCREEN WHEN TESTED AT END OF WEEK 4.	END OF WK 5 CRF'S WERE USED AT FINAL VISIT INSTEAD OF WK 8 CRF'S
Halbreich	71077	56/Female	64	Adverse event	PT STATES "THE BIGGEST REASON (FOR STOPPING DRUG) WAS NOT SLEEPING"	END OF WEEK 7 CRFS WERE USED AS FINAL VISIT.
Munjack	131071	25/Male		Lost to follow-up	.	END OF WEEK 5 CRFS USED AT FINAL VISIT INSTEAD OF CRFS FROM END OF WEEK 8
Oldroyd	321055	38/Male		Lost to follow-up	DID NOT RETURN TO OFFICE FOR END OF WEEK 8 VISIT. FAILURE TO CONTACT. LAST DOSE IS UNKNOWN.	.
Telew	171016	37/Male		Lost to follow-up	PATIENT WAS LOST TO FOLLOW UP, NO WAY TO ASCERTAIN WHEN LAST DOSE WAS	PATIENT'S LAST VISIT WAS VISIT END OF WEEK 7 ON 09/17/99 NO WEEK 8 CRF'S USED

Note: Termination Day is relative to baseline day.

Table EF46

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Reasons of Discontinuation of Drop-out Patients Who Were Classified as Responders (50% Reduction of HAMD-25), Open Phase - ITT, LOCF
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Termination Day	Reason of Discontinuation	Comment	Additional Comment
Thase	181135	31/Female	37	Protocol violation	PT. STOPPED STUDY MED AFTER 4/7/00 DOSE ON HER OWN AND TOOK PROZAC 20MG 4/11/00 SHE STATES SHE SEES HERSELF AS MUCH MORE IRRITABLE BUT DID NOT REPORT	THIS UNTIL 4/11/00
Walsh	171061	47/Female	35	Adverse event	.	.
	171064	21/Female	8	Protocol violation	PT WAS TERMINATE EARLY DUE TO LACK OF COMPLIANCE	.
Zajecka	201092	41/Female	24	Adverse event	.	.

Note: Termination Day is relative to baseline day.

Table EFF1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Percentage of Patients Relapsed - Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

	RBX (N=24)		Placebo (N=22)		Total (N=46)	
	n	%	n	%	n	%
Randomized	24	100.0	22	100.0	46	100.0
Discontinued due to study closure	7	29.2	4	18.2	11	23.9
Discontinued due to other reasons	4	16.7	3	13.6	7	15.2
Relapsed	13	54.2	13	59.1	26	56.5
Completed blinded phase without relapse			2	9.1	2	4.3

Note: 1. One patient who was randomized but subsequently dropped out without any evaluations was excluded from this analysis.
2. Three patients, who were mistakenly randomized, were included in this analysis.

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Product-Limit Survival Estimates
MEDCODE = Placebo

TIMETO	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0.0000	1.0000	0	0	0	20
7.0000				1	19
7.0000	0.9000	0.1000	0.0671	2	18
11.0000				3	17
11.0000	0.8000	0.2000	0.0894	4	16
14.0000*				4	15
15.0000	0.7467	0.2533	0.0981	5	14
15.0000*				5	13
21.0000	0.6892	0.3108	0.1060	6	12
23.0000	0.6318	0.3682	0.1117	7	11
29.0000	0.5744	0.4256	0.1154	8	10
31.0000	0.5169	0.4831	0.1173	9	9
35.0000	0.4595	0.5405	0.1175	10	8
36.0000	0.4021	0.5979	0.1160	11	7
49.0000	0.3446	0.6554	0.1127	12	6
56.0000*				12	5
63.0000	0.2757	0.7243	0.1092	13	4
86.0000*				13	3
140.0000*				13	2
141.0000*				13	1
154.0000*				13	0

* Censored Observation

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Summary Statistics for Time Variable TIMETO

Quantile	Point Estimate	95% Confidence Interval [Lower, Upper)	
75%		35.0000	
50%	35.0000	21.0000	63.0000
25%	15.0000	11.0000	31.0000

Mean 37.1764 Standard Error 5.1564

NOTE: The last observation was censored so the estimate of the mean is biased.

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Product-Limit Survival Estimates
MEDCODE = RBX

TIMETO	Survival	Failure	Survival Standard Error	Number Failed	Number Left
0.0000	1.0000	0	0	0	24
7.0000	0.9583	0.0417	0.0408	1	23
12.0000	0.9167	0.0833	0.0564	2	22
13.0000				3	21
13.0000	0.8333	0.1667	0.0761	4	20
14.0000	0.7917	0.2083	0.0829	5	19
15.0000	0.7500	0.2500	0.0884	6	18
17.0000				7	17
17.0000	0.6667	0.3333	0.0962	8	16
18.0000	0.6250	0.3750	0.0988	9	15
22.0000	0.5833	0.4167	0.1006	10	14
27.0000	0.5417	0.4583	0.1017	11	13
31.0000*				11	12
34.0000	0.4965	0.5035	0.1028	12	11
42.0000	0.4514	0.5486	0.1029	13	10
55.0000*				13	9
69.0000*				13	8
78.0000*				13	7
84.0000*				13	6
85.0000*				13	5
87.0000*				13	4
97.0000*				13	3

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

TIMETO	Survival	Failure	Survival Standard Error	Number Failed	Number Left
111.0000*				13	2
113.0000*				13	1
114.0000*				13	0

* Censored Observation

Summary Statistics for Time Variable TIMETO

Quantile	Point Estimate	95% Confidence Interval [Lower, Upper)	
75%		42.0000	
50%	34.0000	17.0000	
25%	16.0000	13.0000	27.0000

Mean 29.6806 Standard Error 2.8116

NOTE: The last observation was censored so the estimate of the mean is biased.

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Summary of the Number of Censored and Uncensored Values

MEDCODE	Total	Failed	Censored	%Censored
Placebo	20	13	7	35.0000
RBX	24	13	11	45.8333
Total	44	26	18	40.9091

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Survival Function Estimates

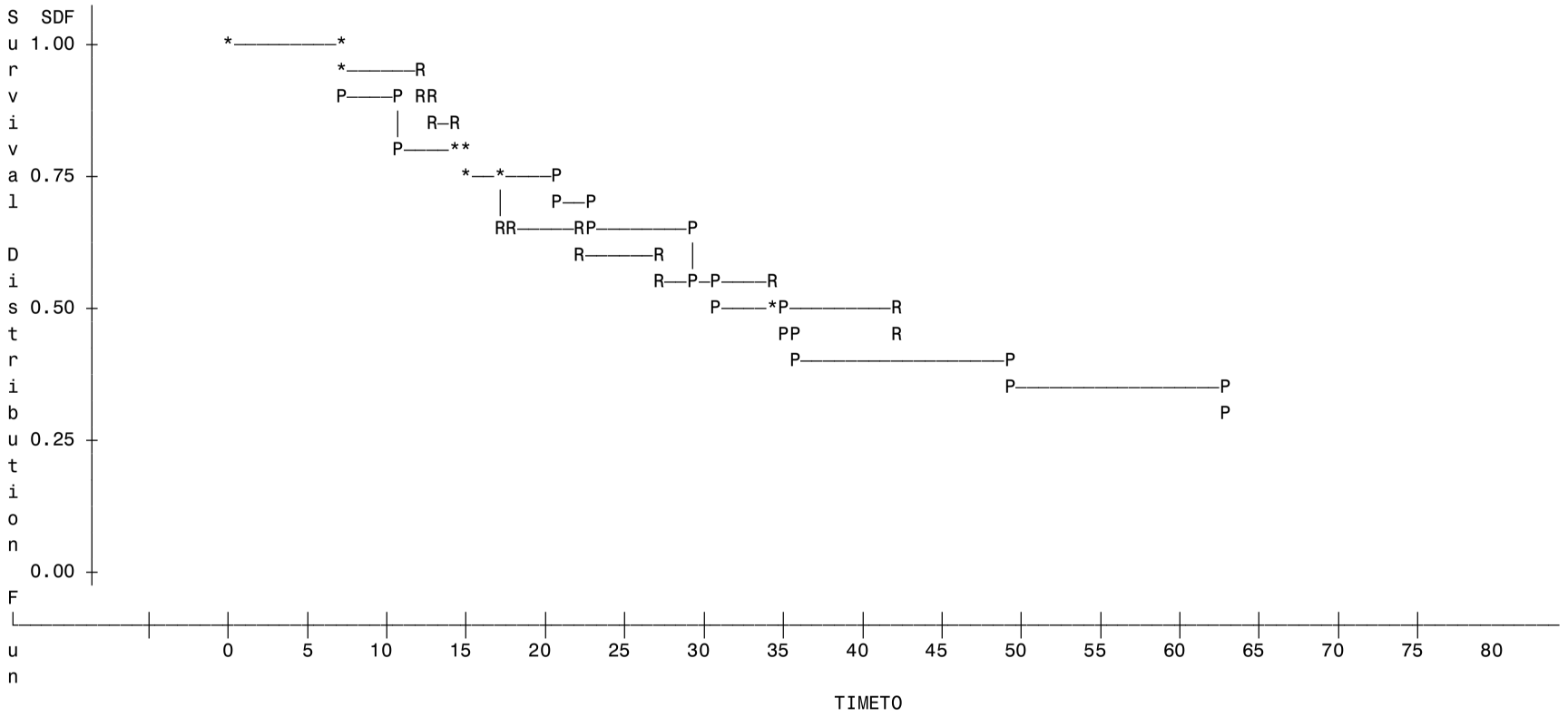

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Censored Observations

Legend for Strata Symbols

P:MEDCODE=Placebo R:MEDCODE=RBX

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Testing Homogeneity of Survival Curves over Strata
Time Variable TIMETO

Rank Statistics

MEDCODE	Log-Rank	Wilcoxon
Placebo	1.7314	32.000
RBX	-1.7314	-32.000

Covariance Matrix for the Log-Rank Statistics

MEDCODE	Placebo	RBX
Placebo	6.27909	-6.27909
RBX	-6.27909	6.27909

Covariance Matrix for the Wilcoxon Statistics

MEDCODE	Placebo	RBX
Placebo	6223.42	-6223.42
RBX	-6223.42	6223.42

Table EFF2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Time (Days) from Randomization to Relapse - Blinded Phase
Randomized Patients

Date Produced: January 12, 2001

The LIFETEST Procedure

Test of Equality over Strata

Test	Chi-Square	DF	Pr > Chi-Square
Log-Rank	0.4774	1	0.4896
Wilcoxon	0.1645	1	0.6850
-2Log(LR)	0.3108	1	0.5772

Table EFF3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patients in Remission at Final Assessment - Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

	----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
	n	%	n	%
Yes	9	37.5	3	13.6
No	15	62.5	19	86.4
Total	24	100.0	22	100.0

Note: A patient is considered to be in remission if the HAMD-25 total score is 7 or less.

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	5.9	6.8
	SD	2.5	3.4
	n	24	22
	Min	2	2
	Max	10	17
Week 9	Mean	7.5	7.0
	SD	4.1	4.0
	n	24	21
	Min	1	1
	Max	19	17
Week 10	Mean	8.5	6.5
	SD	4.8	4.3

(CONTINUED)

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	22	19
	Min	2	2
	Max	22	18
Week 11	Mean	6.8	5.9
	SD	5.0	4.7
	n	16	14
	Min	1	0
	Max	21	16
Week 12	Mean	6.9	6.5
	SD	5.7	3.5
	n	14	11
	Min	0	2

(CONTINUED)

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	24	15
Week 13	Mean	4.8	7.3
	SD	3.5	2.4
	n	13	9
	Min	1	2
	Max	14	11
Week 14	Mean	5.3	5.6
	SD	5.7	2.7
	n	12	9
	Min	1	1
	Max	23	9
Week 15	Mean	4.7	8.4

(CONTINUED)

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	2.1	7.3
	n	10	9
	Min	1	1
	Max	8	25
Week 16	Mean	4.5	7.1
	SD	2.2	5.6
	n	11	8
	Min	1	1
	Max	7	15
Week 20	Mean	4.2	6.9
	SD	2.3	5.0
	n	9	7

(CONTINUED)

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	1	1
	Max	8	14
Week 24	Mean	4.8	4.6
	SD	1.0	5.4
	n	4	5
	Min	4	0
	Max	6	11
Week 28	Mean		5.0
	SD		5.2
	n		5
	Min		0
	Max		12

(CONTINUED)

Table EFF4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-17 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		7.0
	SD		4.6
	n		3
	Min		2
	Max		11

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	8.1	8.6
	SD	3.7	4.3
	n	22	22
	Min	3	2
	Max	16	18
Week 9	Mean	11.0	9.2
	SD	5.6	5.5
	n	24	21
	Min	3	1
	Max	27	25
Week 10	Mean	12.8	9.6
	SD	7.0	6.3

(CONTINUED)

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	4	3
	Max	31	28
Week 11	Mean	9.9	8.1
	SD	8.4	5.5
	n	16	14
	Min	3	1
	Max	36	20
Week 12	Mean	9.6	9.6
	SD	8.2	5.6
	n	14	11
	Min	0	3

(CONTINUED)

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	30	24
Week 13	Mean	7.2	9.7
	SD	5.0	3.7
	n	13	9
	Min	1	3
	Max	20	16
Week 14	Mean	8.0	8.6
	SD	7.9	5.1
	n	12	9
	Min	2	4
	Max	31	20
Week 15	Mean	5.8	12.6

(CONTINUED)

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	1.8	9.4
	n	9	9
	Min	3	4
	Max	8	34
Week 16	Mean	5.3	8.6
	SD	2.4	6.3
	n	10	8
	Min	2	1
	Max	10	16
Week 20	Mean	4.6	9.0
	SD	3.0	6.0
	n	8	7

(CONTINUED)

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	1	2
	Max	9	15
Week 24	Mean	4.3	5.4
	SD	1.7	6.1
	n	4	5
	Min	2	0
	Max	6	13
Week 28	Mean		5.2
	SD		5.2
	n		5
	Min		0
	Max		12

(CONTINUED)

Table EFF5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-25 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		8.0
	SD		4.6
	n		3
	Min		3
	Max		12

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	7.9	8.4
	SD	3.3	3.6
	n	24	22
	Min	3	3
	Max	15	18
Week 9	Mean	9.5	9.1
	SD	4.8	5.5
	n	24	21
	Min	2	2
	Max	21	27
Week 10	Mean	11.2	9.2
	SD	6.5	5.8

(CONTINUED)

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	22	19
	Min	4	3
	Max	27	23
Week 11	Mean	8.0	8.3
	SD	5.5	4.9
	n	16	14
	Min	2	2
	Max	24	19
Week 12	Mean	8.3	9.0
	SD	6.8	4.9
	n	14	11
	Min	0	3

(CONTINUED)

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	28	21
Week 13	Mean	6.0	10.1
	SD	4.6	3.2
	n	13	9
	Min	2	5
	Max	18	15
Week 14	Mean	6.3	7.6
	SD	6.8	3.2
	n	12	9
	Min	2	2
	Max	27	12
Week 15	Mean	5.9	10.9

(CONTINUED)

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	2.4	7.2
	n	10	9
	Min	3	4
	Max	11	27
Week 16	Mean	5.7	9.3
	SD	2.9	7.4
	n	11	8
	Min	2	2
	Max	10	21
Week 20	Mean	4.8	10.0
	SD	2.8	5.4
	n	9	7

(CONTINUED)

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	1	3
	Max	10	17
Week 24	Mean	5.3	6.0
	SD	1.0	6.1
	n	4	5
	Min	4	0
	Max	6	14
Week 28	Mean		5.4
	SD		5.4
	n		5
	Min		0
	Max		12

(CONTINUED)

Table EFF6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

HAMD-28 Total Scores: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		8.0
	SD		5.3
	n		3
	Min		2
	Max		12

Table EFF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness by treatment group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Day 57	Normal, not at all ill	4	16.7	4	18.2
	Borderline ill	15	62.5	10	45.5
	Mildly ill	5	20.8	8	36.4
	Total	24	100.0	22	100.0
Week 10	Normal, not at all ill	1	4.2	3	14.3
	Borderline ill	11	45.8	8	38.1
	Mildly ill	6	25.0	6	28.6
	Moderately ill	6	25.0	3	14.3
	Markedly ill			1	4.8
	Total	24	100.0	21	100.0
Week 12	Normal, not at all ill	2	12.5	2	15.4

(CONTINUED)

Table EFF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness by treatment group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 12	Borderline ill	8	50.0	3	23.1
	Mildly ill	3	18.8	6	46.2
	Moderately ill	2	12.5	2	15.4
	Markedly ill	1	6.3		
	Total	16	100.0	13	100.0
Week 14	Normal, not at all ill	4	30.8	3	27.3
	Borderline ill	5	38.5	2	18.2
	Mildly ill	3	23.1	3	27.3
	Moderately ill			3	27.3
	Markedly ill	1	7.7		
	Total	13	100.0	11	100.0

(CONTINUED)

Table EFF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness by treatment group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 16	Normal, not at all ill	5	45.5	2	22.2
	Borderline ill	5	45.5	2	22.2
	Mildly ill	1	9.1	4	44.4
	Moderately ill			1	11.1
	Total	11	100.0	9	100.0
Week 20	Normal, not at all ill	3	33.3	2	28.6
	Borderline ill	6	66.7	1	14.3
	Mildly ill			3	42.9
	Moderately ill			1	14.3
	Total	9	100.0	7	100.0
Week 24	Normal, not at all ill	1	25.0	2	40.0

(CONTINUED)

Table EFF7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Severity of Illness by treatment group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 24	Borderline ill	3	75.0	1	20.0
	Mildly ill			2	40.0
	Total	4	100.0	5	100.0
Week 28	Normal, not at all ill			2	40.0
	Borderline ill			2	40.0
	Mildly ill			1	20.0
	Total			5	100.0
Week 32	Normal, not at all ill			1	33.3
	Borderline ill			1	33.3
	Mildly ill			1	33.3
	Total			3	100.0

Table EFF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvements by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Day 57	Very much improved	4	16.7	4	18.2
	Much improved	15	62.5	10	45.5
	Minimally improved	5	20.8	8	36.4
	Total	24	100.0	22	100.0
Week 10	Very much improved	1	4.2	3	14.3
	Much improved	11	45.8	8	38.1
	Minimally improved	6	25.0	6	28.6
	No change	6	25.0	3	14.3
	Minimally worse			1	4.8
	Total	24	100.0	21	100.0
Week 12	Very much improved	2	12.5	2	15.4

(CONTINUED)

Table EFF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvements by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 12	Much improved	8	50.0	3	23.1
	Minimally improved	3	18.8	6	46.2
	No change	2	12.5	2	15.4
	Minimally worse	1	6.3		
	Total	16	100.0	13	100.0
Week 14	Very much improved	4	30.8	3	27.3
	Much improved	5	38.5	2	18.2
	Minimally improved	3	23.1	3	27.3
	No change			3	27.3
	Minimally worse	1	7.7		
	Total	13	100.0	11	100.0

(CONTINUED)

Table EFF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvements by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 16	Very much improved	5	45.5	2	22.2
	Much improved	5	45.5	2	22.2
	Minimally improved	1	9.1	4	44.4
	No change			1	11.1
	Total	11	100.0	9	100.0
Week 20	Very much improved	3	33.3	2	28.6
	Much improved	6	66.7	1	14.3
	Minimally improved			3	42.9
	No change			1	14.3
	Total	9	100.0	7	100.0
Week 24	Very much improved	1	25.0	2	40.0

(CONTINUED)

Table EFF8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions: Global Improvements by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Week 24	Much improved	3	75.0	1	20.0
	Minimally improved			2	40.0
	Total	4	100.0	5	100.0
Week 28	Very much improved			2	40.0
	Much improved			2	40.0
	Minimally improved			1	20.0
	Total			5	100.0
Week 32	Very much improved			1	33.3
	Much improved			1	33.3
	Minimally improved			1	33.3
	Total			3	100.0

Table EFF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions Efficacy Index: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	2.2	2.1
	SD	0.8	0.9
	n	24	22
	Min	2	1
	Max	4	4
Week 10	Mean	1.6	2.0
	SD	0.8	1.2
	n	23	21
	Min	0	1
	Max	3	4
Week 12	Mean	2.1	2.2
	SD	1.3	1.2

(CONTINUED)

Table EFF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions Efficacy Index: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	13
	Min	1	1
	Max	4	4
Week 14	Mean	2.3	1.8
	SD	1.4	1.0
	n	13	11
	Min	1	1
	Max	4	4
Week 16	Mean	3.1	2.3
	SD	1.3	1.4
	n	11	9
	Min	1	1

(CONTINUED)

Table EFF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions Efficacy Index: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	4	4
Week 20	Mean	3.1	2.1
	SD	1.4	1.5
	n	9	7
	Min	1	1
	Max	4	4
Week 24	Mean	2.8	2.6
	SD	1.5	1.5
	n	4	5
	Min	1	1
	Max	4	4
Week 28	Mean		2.7

(CONTINUED)

Table EFF9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Clinical Global Impressions Efficacy Index: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		1.8
	n		5
	Min		1
	Max		4
Week 32	Mean		2.0
	SD		1.7
	n		3
	Min		1
	Max		4

Table EFF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	7.7	7.1
	SD	1.0	1.7
	n	24	22
	Min	6	1
	Max	10	9
Week 10	Mean	6.7	6.4
	SD	1.2	2.0
	n	23	20
	Min	5	2
	Max	9	10
Week 12	Mean	7.0	6.7
	SD	1.4	1.9

(CONTINUED)

Table EFF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	14
	Min	4	3
	Max	9	10
Week 14	Mean	7.4	6.8
	SD	1.3	2.3
	n	13	11
	Min	5	3
	Max	10	10
Week 16	Mean	7.9	7.3
	SD	1.0	1.8
	n	11	9
	Min	6	4

(CONTINUED)

Table EFF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	10	10
Week 20	Mean	7.3	8.0
	SD	1.8	1.7
	n	9	7
	Min	3	6
	Max	9	10
Week 24	Mean	8.8	8.6
	SD	1.0	1.5
	n	4	5
	Min	8	7
	Max	10	10
Week 28	Mean		8.4

(CONTINUED)

Table EFF10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Patient Global Impressions: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		1.1
	n		5
	Min		7
	Max		10
Week 32	Mean		8.0
	SD		1.0
	n		3
	Min		7
	Max		9

Table EFF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Montgomery-Asberg Depression Rating Scale Total Score: Summary Statistics Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	6.9	7.4
	SD	4.2	5.0
	n	24	22
	Min	0	0
	Max	14	18
Week 10	Mean	12.1	8.8
	SD	7.4	8.2
	n	23	21
	Min	2	0
	Max	29	24
Week 12	Mean	10.9	8.9
	SD	10.7	7.6

(CONTINUED)

Table EFF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Montgomery-Asberg Depression Rating Scale Total Score: Summary Statistics Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	13
	Min	0	0
	Max	37	24
Week 14	Mean	8.3	7.8
	SD	8.6	5.8
	n	13	11
	Min	0	0
	Max	32	19
Week 16	Mean	3.9	9.0
	SD	3.1	6.5
	n	11	9
	Min	0	0

(CONTINUED)

Table EFF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Montgomery-Asberg Depression Rating Scale Total Score: Summary Statistics Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	10	17
Week 20	Mean	3.3	8.1
	SD	2.8	6.0
	n	9	7
	Min	1	2
	Max	9	16
Week 24	Mean	5.3	5.2
	SD	1.3	5.4
	n	4	5
	Min	4	0
	Max	7	11
Week 28	Mean		4.2

(CONTINUED)

Table EFF11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Montgomery-Asberg Depression Rating Scale Total Score: Summary Statistics Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		3.3
	n		5
	Min		0
	Max		8
Week 32	Mean		7.0
	SD		6.0
	n		3
	Min		1
	Max		13

Table EFF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Depression Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	5.3	5.4
	SD	3.5	3.2
	n	24	22
	Min	2	2
	Max	12	13
Week 10	Mean	6.8	5.9
	SD	3.9	3.9
	n	23	20
	Min	2	1
	Max	15	14
Week 12	Mean	6.4	5.7
	SD	4.5	3.5

(CONTINUED)

Table EFF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Depression Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	14
	Min	2	2
	Max	14	14
Week 14	Mean	5.5	4.8
	SD	4.1	4.6
	n	13	11
	Min	2	1
	Max	12	13
Week 16	Mean	3.2	4.8
	SD	2.7	3.3
	n	11	9
	Min	2	2

(CONTINUED)

Table EFF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Depression Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	11	12
Week 20	Mean	4.9	3.1
	SD	4.0	1.5
	n	9	7
	Min	1	1
	Max	11	5
Week 24	Mean	3.3	4.0
	SD	1.0	1.4
	n	4	5
	Min	2	2
	Max	4	5
Week 28	Mean		4.0

(CONTINUED)

Table EFF12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Depression Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		1.6
	n		5
	Min		2
	Max		6
Week 32	Mean		4.0
	SD		1.7
	n		3
	Min		3
	Max		6

Table EFF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anxiety Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	4.5	7.1
	SD	3.6	5.6
	n	24	22
	Min	0	0
	Max	13	21
Week 10	Mean	7.9	7.8
	SD	5.3	5.9
	n	23	20
	Min	0	0
	Max	15	20
Week 12	Mean	6.6	6.5
	SD	6.8	5.5

(CONTINUED)

Table EFF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anxiety Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	14
	Min	0	0
	Max	21	20
Week 14	Mean	6.5	6.3
	SD	6.1	3.6
	n	13	11
	Min	0	0
	Max	16	12
Week 16	Mean	4.7	4.9
	SD	5.4	3.6
	n	11	9
	Min	0	0

(CONTINUED)

Table EFF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anxiety Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	14	11
Week 20	Mean	5.1	5.6
	SD	5.3	4.1
	n	9	7
	Min	0	0
	Max	14	9
Week 24	Mean	2.8	3.8
	SD	2.2	4.1
	n	4	5
	Min	0	0
	Max	5	9
Week 28	Mean		5.6

(CONTINUED)

Table EFF13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anxiety Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		4.2
	n		5
	Min		1
	Max		9
Week 32	Mean		4.7
	SD		2.5
	n		3
	Min		2
	Max		7

Table EFF14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Somatic Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	5.5	6.5
	SD	3.3	3.1
	n	24	22
	Min	1	2
	Max	15	15
Week 10	Mean	5.4	6.8
	SD	3.4	4.2
	n	23	20
	Min	0	2
	Max	11	18
Week 12	Mean	6.1	6.1
	SD	4.1	3.5

(CONTINUED)

Table EFF14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Somatic Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	14
	Min	0	1
	Max	14	13
Week 14	Mean	4.9	5.5
	SD	2.4	3.1
	n	13	11
	Min	0	1
	Max	9	13
Week 16	Mean	4.7	6.0
	SD	1.8	3.1
	n	11	9
	Min	2	1

(CONTINUED)

Table EFF14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Somatic Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	8	10
Week 20	Mean	4.6	5.9
	SD	3.3	3.2
	n	9	7
	Min	1	2
	Max	11	12
Week 24	Mean	2.5	4.0
	SD	1.7	2.0
	n	4	5
	Min	0	1
	Max	4	6
Week 28	Mean		4.6

(CONTINUED)

Table EFF14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Somatic Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		2.1
	n		5
	Min		2
	Max		7
Week 32	Mean		4.7
	SD		1.5
	n		3
	Min		3
	Max		6

Table EFF15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anger-Hostility Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Day 57	Mean	4.4	5.1
	SD	3.3	4.2
	n	24	22
	Min	0	0
	Max	13	18
Week 10	Mean	8.4	6.4
	SD	7.0	5.6
	n	23	20
	Min	0	0
	Max	21	22
Week 12	Mean	5.8	6.6
	SD	6.2	5.8

(CONTINUED)

Table EFF15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anger-Hostility Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	n	16	14
	Min	0	0
	Max	20	18
Week 14	Mean	6.0	4.7
	SD	4.7	3.4
	n	13	11
	Min	0	0
	Max	15	12
Week 16	Mean	2.9	5.3
	SD	3.1	4.3
	n	11	9
	Min	0	0

(CONTINUED)

Table EFF15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anger-Hostility Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 16	Max	8	12
Week 20	Mean	5.1	6.1
	SD	4.8	5.0
	n	9	7
	Min	0	0
	Max	12	13
Week 24	Mean	4.3	4.2
	SD	4.9	5.8
	n	4	5
	Min	0	0
	Max	9	12
Week 28	Mean		3.6

(CONTINUED)

Table EFF15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Kellner Symptom Questionnaire Anger-Hostility Cluster: Summary Statistics by Treatment Group, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 28	SD		3.9
	n		5
	Min		0
	Max		9
Week 32	Mean		5.7
	SD		4.0
	n		3
	Min		2
	Max		10

Table EFF16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Rush Sexual Inventory: Patients' Condition at Baseline - Randomized Patients
All Randomized Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Sexual dysfunction on medication?	Yes	14	58.3	11	50.0
	No	10	41.7	11	50.0
You/partner using birth control?	Yes	13	54.2	7	31.8
	No	4	16.7	6	27.3
	Not Applicable	7	29.2	9	40.9
Ever has surgical/medical procedures on reproductive organs?	Yes	9	37.5	10	45.5
	No	15	62.5	12	54.5
Ever has any non-routine investigation of reproductive organ?	Yes	5	20.8	2	9.1
	No	19	79.2	20	90.9
Ever been investigated for sexual dysfunction?	Yes	3	12.5		
	No	21	87.5	22	100.0

(CONTINUED)

Table EFF16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Rush Sexual Inventory: Patients' Condition at Baseline - Randomized Patients
All Randomized Patients

Date Produced: January 12, 2001

		----- Reboxetine ---- (N=24)		------ Placebo ------ (N=22)	
		n	%	n	%
Ever received treatment for sexual dysfunction?	Yes	2	8.3		
	No	22	91.7	22	100.0

Table EFF17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Week 8		Week 16		Week 32/Final	
		RBX	Placebo	RBX	Placebo	RBX	Placebo
Frequency of Pleasurable Thoughts	Means	45.5	50.6	38.9	53.0	39.0	45.4
	SD	29.9	27.0	33.0	34.7	30.8	25.3
	n	22	20	9	7	20	18
	Min	0	2	0	1	0	1
	Max	96	97	94	89	98	80
Ability to Become Sexually Excited	Means	44.2	55.1	54.2	68.9	46.1	56.3
	SD	33.4	27.3	37.2	23.6	35.3	24.8
	n	18	19	11	7	20	19
	Min	0	3	1	41	0	4
	Max	94	94	96	99	96	98
Frequency of Desires to Inititate Sexual Activity	Means	41.8	51.7	51.6	42.9	34.5	42.7
	SD	32.2	31.5	39.2	38.7	32.3	26.8

(CONTINUED)

Table EFF17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Week 8		Week 16		Week 32/Final	
		RBX	Placebo	RBX	Placebo	RBX	Placebo
Frequency of Desires to Inititate Sexual Activity	n	21	19	11	7	19	16
	Min	0	1	1	2	0	2
	Max	95	94	99	91	98	85
Frequency of Initiating Sexual Activity	Means	28.3	33.2	33.8	31.2	28.9	34.8
	SD	30.1	27.8	30.8	31.7	28.4	24.1
	n	19	19	10	6	16	18
	Min	0	1	1	1	0	0
	Max	95	93	87	71	86	87
Overall Degree of Sexual Satisfaction Attained	Means	42.3	49.0	33.5	52.3	35.8	50.4
	SD	33.1	32.0	29.1	33.1	31.4	28.9
	n	18	22	11	7	19	16
	Min	0	1	1	11	0	0

(CONTINUED)

Table EFF17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Visual Analogue Scales, Summary by Visit, Blinded Phase - Observed
All Enrolled Patients

Date Produced: January 12, 2001

		Week 8		Week 16		Week 32/Final	
		RBX	Placebo	RBX	Placebo	RBX	Placebo
Overall Degree of Sexual Satisfaction Attained	Max	94	95	86	98	86	97

Table EFF18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
Masturbation	Never	13	54.2	9	40.9	3	27.3	2	28.6	11	52.4	7	36.8
	Once a Week	3	12.5	6	27.3	3	27.3	4	57.1	3	14.3	4	21.1
	2-4 Times Per Week	8	33.3	7	31.8	5	45.5	1	14.3	7	33.3	8	42.1
	Total	24	100.0	22	100.0	11	100.0	7	100.0	21	100.0	19	100.0
Intercourse	Never	11	45.8	13	59.1	4	36.4	6	85.7	11	52.4	11	57.9
	Once a Week	8	33.3	9	40.9	6	54.5	1	14.3	8	38.1	8	42.1
	2-4 Times Per Week	5	20.8			1	9.1			2	9.5		
	Total	24	100.0	22	100.0	11	100.0	7	100.0	21	100.0	19	100.0
Oral Sex	Never	18	75.0	14	63.6	7	63.6	7	100.0	16	76.2	12	63.2
	Once a Week	5	20.8	6	27.3	4	36.4			5	23.8	5	26.3
	2-4 Times Per Week	1	4.2	2	9.1							2	10.5

(CONTINUED)

Table EFF18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Frequency of Sexual Activities in the Past Four Weeks, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
Oral Sex	Total	24	100.0	22	100.0	11	100.0	7	100.0	21	100.0	19	100.0

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
1. Spontaneous daytime erections	Yes	2	18.2	1	16.7	1	14.3			3	30.0		
	No	9	81.8	5	83.3	6	85.7	4	100.0	7	70.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
2. Painful erections	Yes									1	10.0		
	No	11	100.0	6	100.0	7	100.0	4	100.0	9	90.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
3. Erection when sexually aroused	Yes	9	81.8	5	83.3	6	85.7	3	75.0	8	80.0	6	100.0
	No	2	18.2	1	16.7	1	14.3	1	25.0	2	20.0		
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
4. Difficulty getting an erection when sexually stimulated	Yes	3	27.3	1	16.7	2	28.6	1	25.0	4	40.0		
	No	8	72.7	5	83.3	5	71.4	3	75.0	6	60.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
4. Difficulty getting an erection when sexually stimulated	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
5. Difficulty maintaining an erection to complete sexual act	Yes	3	27.3	2	33.3	3	42.9	1	25.0	3	30.0	1	16.7
	No	8	72.7	4	66.7	4	57.1	3	75.0	7	70.0	5	83.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
6. Waking up from sleep with an erection	Yes	5	45.5	4	66.7	4	57.1	3	75.0	4	40.0	3	50.0
	No	6	54.5	2	33.3	3	42.9	1	25.0	6	60.0	3	50.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
7. Requiring more stimuli than usual to achieve an erection	Yes	7	63.6	2	33.3	3	42.9	1	25.0	5	50.0		
	No	4	36.4	4	66.7	4	57.1	3	75.0	5	50.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
8. Requiring more stimuli than usual to maintain an erection	Yes	4	36.4	3	50.0	2	28.6	1	25.0	5	50.0	1	16.7
	No	7	63.6	3	50.0	5	71.4	3	75.0	5	50.0	5	83.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
9. Decreased fullness of erection	Yes	6	54.5	1	16.7	4	57.1	1	25.0	6	60.0	2	33.3
	No	5	45.5	5	83.3	3	42.9	3	75.0	4	40.0	4	66.7
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
10. Increased sensitivity of genitals upon physical stimulation	Yes	1	9.1			1	14.3						
	No	10	90.9	6	100.0	6	85.7	4	100.0	10	100.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
11. Decreased sensitivity of genitals upon physical stimulation	Yes	2	18.2			1	14.3			2	20.0		
	No	9	81.8	6	100.0	6	85.7	4	100.0	8	80.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
12. Orgasm	Yes	9	81.8	5	83.3	6	85.7	3	75.0	9	90.0	5	83.3
	No	2	18.2	1	16.7	1	14.3	1	25.0	1	10.0	1	16.7
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
13. Ejaculation	Yes	9	81.8	5	83.3	6	85.7	3	75.0	9	90.0	4	66.7
	No	2	18.2	1	16.7	1	14.3	1	25.0	1	10.0	2	33.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
14. Painful orgasm/ejaculation	Yes			1	16.7					1	10.0		
	No	11	100.0	5	83.3	7	100.0	4	100.0	9	90.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
14. Painful orgasm/ejaculation	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
15. Orgasm without ejaculation	Yes	2	18.2	1	16.7					1	10.0	1	16.7
	No	9	81.8	5	83.3	7	100.0	4	100.0	9	90.0	5	83.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
16. Delay in achieving orgasm/ejaculation but eventually doing so	Yes	1	9.1			1	14.3			1	10.0	1	16.7
	No	10	90.9	6	100.0	6	85.7	4	100.0	9	90.0	5	83.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
17. Inability to achieve orgasm/ejaculation	Yes	2	18.2	1	16.7	1	14.3	1	25.0	1	10.0	2	33.3
	No	9	81.8	5	83.3	6	85.7	3	75.0	9	90.0	4	66.7
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
18. Orgasm without erection	Yes	4	36.4			1	16.7			2	20.0		
	No	7	63.6	6	100.0	5	83.3	4	100.0	8	80.0	6	100.0
	Total	11	100.0	6	100.0	6	100.0	4	100.0	10	100.0	6	100.0
19. Orgasm occurring during sleep	No	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
20. Genital pain during sexual contact	No	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
21. Orgasm/ejaculation occurring earlier than desired	Yes	5	45.5	2	33.3	3	42.9	1	25.0	6	60.0	1	16.7
	No	6	54.5	4	66.7	4	57.1	3	75.0	4	40.0	5	83.3
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0

(CONTINUED)

Table EFF19

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Male Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
22. Experiencing orgasm without sexual provocation (spontaneously, except in sleep)	No	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0
23. Generally decreased intensity of orgasm	Yes	3	27.3	2	33.3	2	28.6			2	20.0		
	No	8	72.7	4	66.7	5	71.4	4	100.0	8	80.0	6	100.0
	Total	11	100.0	6	100.0	7	100.0	4	100.0	10	100.0	6	100.0

Table EFF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
1. Increased sensitivity, other than pain, in breasts upon physical contact	Yes	5	38.5	1	6.3	1	25.0			2	18.2	2	15.4
	No	8	61.5	15	93.8	3	75.0	3	100.0	9	81.8	11	84.6
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
2. Increased sensitivity of genitals, other than pain, upon physical contact	Yes	4	30.8	3	18.8	1	25.0			2	18.2	2	15.4
	No	9	69.2	13	81.3	3	75.0	3	100.0	9	81.8	11	84.6
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
3. Pain in breasts upon physical contact	Yes			2	12.5			1	33.3			1	7.7
	No	13	100.0	14	87.5	4	100.0	2	66.7	11	100.0	12	92.3
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
4. Pain in genitals upon physical contact	Yes											1	7.7
	No	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	12	92.3

(CONTINUED)

Table EFF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
4. Pain in genitals upon physical contact	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
5. Decreased sensitivity in breasts upon physical contact	Yes	1	7.7							1	9.1		
	No	12	92.3	16	100.0	4	100.0	3	100.0	10	90.9	13	100.0
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
6. Decreased sensitivity in genitals upon physical contact	Yes			1	6.3					1	9.1		
	No	13	100.0	15	93.8	4	100.0	3	100.0	10	90.9	13	100.0
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
7. Inadequate swelling or vaginal lubrication during sexual contact	Yes	1	7.7			1	25.0			3	27.3		
	No	12	92.3	16	100.0	3	75.0	3	100.0	8	72.7	13	100.0
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0

(CONTINUED)

Table EFF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
8. Orgasm	Yes	8	61.5	9	56.3	2	50.0	1	33.3	5	45.5	8	61.5
	No	5	38.5	7	43.8	2	50.0	2	66.7	6	54.5	5	38.5
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
9. Multiple orgasm	Yes	3	23.1	2	12.5	1	25.0			2	18.2	3	23.1
	No	10	76.9	14	87.5	3	75.0	3	100.0	9	81.8	10	76.9
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
10. Difficulty achieving orgasm, but eventually being able to	Yes	4	30.8	4	25.0	1	25.0	1	33.3	4	36.4	6	46.2
	No	9	69.2	12	75.0	3	75.0	2	66.7	7	63.6	7	53.8
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
11. Inability to achieve orgasm	Yes	1	7.7	3	18.8					2	18.2	2	15.4
	No	12	92.3	13	81.3	4	100.0	3	100.0	9	81.8	11	84.6

(CONTINUED)

Table EFF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
11. Inability to achieve orgasm	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
12. Experiencing orgasm without sexual provocation (spontaneously)	Yes	2	15.4	4	25.0	1	25.0					2	15.4
	No	11	84.6	12	75.0	3	75.0	3	100.0	11	100.0	11	84.6
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
13. Painful orgasm	No	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
14. Decreased intensity or orgasm	Yes			1	6.3	1	25.0			1	9.1	2	15.4
	No	13	100.0	15	93.8	3	75.0	3	100.0	10	90.9	11	84.6
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0

(CONTINUED)

Table EFF20

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

RSI: Summary of Female Patients' Response to Yes/No Items, Blinded Phase - Observed
All Randomized Patients

Date Produced: January 12, 2001

		Week 8				Week 16				Week 32/Final			
		RBX		Placebo		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%	n	%	n	%
15. Involuntary vaginal contractions that prevent vaginal penetration	No	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	13	100.0
16. Physical pain during sexual activity	Yes	1	7.7					1	33.3			1	8.3
	No	12	92.3	16	100.0	4	100.0	2	66.7	11	100.0	11	91.7
	Total	13	100.0	16	100.0	4	100.0	3	100.0	11	100.0	12	100.0

Table SM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Usual Daily Dose of Study Medication by Week - Open Phase
All Enrolled Patients

Date Produced: December 19, 2000

	Week 5		Week 6		Week 7		Week 8/ Final Visit	
	n	%	n	%	n	%	n	%
2 tablets	34	35.8	25	28.1	19	23.2	41	36.0
2.5 tablets	61	64.2	64	71.9	63	76.8	72	63.2
Other							1	0.9
Total Reported	95	100.0	89	100.0	82	100.0	114	100.0

Table SM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Usual Daily Dose of Study Medication by Week - Blinded Phase
All Enrolled Patients

Date Produced: December 19, 2000

Visit		RBX (N=24)		Placebo (N=22)	
		n	%	n	%
Week 9	2 tablets	5	21.7	6	28.6
	2.5 tablets	18	78.3	15	71.4
	Total Reported	23	100.0	21	100.0
Week 10	2 tablets	5	31.3	3	20.0
	2.5 tablets	11	68.8	12	80.0
	Total Reported	16	100.0	15	100.0
Week 11	2 tablets	5	35.7	3	21.4
	2.5 tablets	9	64.3	11	78.6
	Total Reported	14	100.0	14	100.0
Week 12	2 tablets	6	46.2	3	27.3
	2.5 tablets	7	53.8	8	72.7
	Total Reported	13	100.0	11	100.0

(CONTINUED)

Table SM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Usual Daily Dose of Study Medication by Week - Blinded Phase
All Enrolled Patients

Date Produced: December 19, 2000

Visit		RBX (N=24)		Placebo (N=22)	
		n	%	n	%
Week 13	2 tablets	3	25.0	2	25.0
	2.5 tablets	9	75.0	6	75.0
	Total Reported	12	100.0	8	100.0
Week 14	2 tablets	2	18.2	2	22.2
	2.5 tablets	9	81.8	7	77.8
	Total Reported	11	100.0	9	100.0
Week 15	2 tablets	1	10.0	2	25.0
	2.5 tablets	9	90.0	6	75.0
	Total Reported	10	100.0	8	100.0
Week 16	2 tablets	2	18.2	2	28.6
	2.5 tablets	8	72.7	5	71.4
	Other	1	9.1		

(CONTINUED)

Table SM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Usual Daily Dose of Study Medication by Week - Blinded Phase
All Enrolled Patients

Date Produced: December 19, 2000

Visit		RBX (N=24)		Placebo (N=22)	
		n	%	n	%
Week 16	Total Reported	11	100.0	7	100.0
Week 20	2 tablets	1	25.0	1	20.0
	2.5 tablets	3	75.0	4	80.0
	Total Reported	4	100.0	5	100.0
Week 24	2 tablets			1	20.0
	2.5 tablets			4	80.0
	Total Reported			5	100.0
Week 28	2 tablets			1	33.3
	2.5 tablets			2	66.7
	Total Reported			3	100.0
Week 32/Final Visit	2 tablets	4	17.4	5	26.3
	2.5 tablets	19	82.6	14	73.7

(CONTINUED)

Table SM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Usual Daily Dose of Study Medication by Week - Blinded Phase
All Enrolled Patients

Date Produced: December 19, 2000

Visit		RBX (N=24)		Placebo (N=22)	
		n	%	n	%
Week 32/Final Visit	Total Reported	23	100.0	19	100.0

Table AE1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System
All Enrolled Patients

Date Produced: January 18, 2001

Body System	--- Patients --- (N=128)		# of Reports
	n	%	
No of AE reported			99
Patients with at least one AE	55	43.0	
Body	18	14.1	20
Cardiovascular	5	3.9	5
Digestive	19	14.8	22
Metabolic and Nutritional	1	0.8	1
Nervous	25	19.5	35
Respiratory	2	1.6	3
Skin	4	3.1	4
Special Senses	2	1.6	2
Urogenital	6	4.7	7

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				99
Patients with at least one AE		55	43.0	
Body	ABDOMINAL DISTENSION	1	0.8	1
	ASTHENIA	2	1.6	2
	BACK PAIN	1	0.8	1
	FATIGUE	4	3.1	4
	GENERALIZED PAIN	1	0.8	1
	HEADACHE	5	3.9	5
	REACTION UNEVALUABLE	1	0.8	1
	TRAUMA	3	2.3	4

(CONTINUED)

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	UPPER RESPIRATORY INFECTION	1	0.8	1
Cardiovascular	CARDIAC RHYTHM ABNORMAL	1	0.8	1
	HYPERTENSION	1	0.8	1
	TACHYCARDIA	1	0.8	1
	VASODILATION	2	1.6	2
Digestive	APPETITE DECREASED	1	0.8	1
	APPETITE INCREASED	1	0.8	1
	CONSTIPATION	1	0.8	1
	DIARRHEA	1	0.8	1
	DRY MOUTH	9	7.0	9

(CONTINUED)

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	DYSPEPSIA	2	1.6	2
	ERUCTATION	1	0.8	1
	GASTROESOPHAGEAL REFLUX	1	0.8	1
	LIVER FUNCTION TESTS ABNORMAL NOS	1	0.8	1
	LOOSE STOOLS NEC	1	0.8	1
	NAUSEA	1	0.8	1
	TOOTHACHE	1	0.8	1
	VOMITING	1	0.8	1
Metabolic and Nutritional	WEIGHT INCREASE	1	0.8	1

(CONTINUED)

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	AGITATION	1	0.8	1
	ANXIETY	2	1.6	2
	APATHY	1	0.8	1
	ATAXIA	1	0.8	1
	CNS STIMULATION	1	0.8	1
	HYPERTONIA	2	1.6	2
	INSOMNIA	7	5.5	8
	LIBIDO DECREASED	7	5.5	7
	NIGHTMARES	1	0.8	1
	PARESTHESIA	1	0.8	1

(CONTINUED)

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	SOMNOLENCE	8	6.3	8
	TREMOR	2	1.6	2
Respiratory	PHARYNGITIS	1	0.8	1
	SINUSITIS	1	0.8	2
Skin	DIAPHORETIC	3	2.3	3
	HERPES ZOSTER	1	0.8	1
Special Senses	BLURRED VISION	1	0.8	1
	TINNITUS	1	0.8	1
Urogenital	EJACULATION ABNORMAL	1	0.8	1
	RETENTION URINARY	1	0.8	1

(CONTINUED)

Table AE2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events That Started before Treatment - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	SEXUAL FUNCTION ABNORMAL	4	3.1	4
	URINATION IMPAIRED	1	0.8	1

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Amsterdam	11133	41/Male	Skin	HERPES ZOSTER	SHINGLES	64	-14	25	No	Severe	No	None	Recovered
	11167	53/Female	Cardiovascular	VASODILATION	HOT FLASHES	61	-19		No	Moderate	No	None	Not recovered
Croft	231001	50/Female	Urogenital	RETENTION URINARY	URINE RETENTION	128			No	Moderate	Yes	None	Not recovered
	231002	40/Female	Body	FATIGUE	FATIGUE	28			No	Moderate	No	None	Not recovered
	231080	55/Female	Cardiovascular	CARDIAC RHYTHM ABNORMAL	CARDIAC ARRYTHMIA	50	-51		No	Moderate	No	None	Not recovered
			Nervous	AGITATION	AGITATION	50	-55	15	No	Moderate	No	None	Recovered
	231119	56/Female	Body	ABDOMINAL DISTENSION	BLOATING (ABDOMEN)	75		0	No	Moderate	No	None	Recovered
			Nervous	ANXIETY	JITTERINESS	75		25	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Croft	231120	54/Female	Digestive	DRY MOUTH	DRY MOUTH	68			No	Severe	No	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	68		54	No	Severe	No	None	Recovered
	231139	36/Female	Nervous	INSOMNIA	INSOMNIA	59		50	No	Moderate	No	None	Recovered
Delgado	41069	41/Female	Digestive	APPETITE INCREASED	INCREASED APPETITE	71		37	No	Severe	No	None	Recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	71		37	No	Severe	No	None	Recovered
	41070	46/Female	Digestive	DRY MOUTH	DRY MOUTH	63			No	Severe	Yes	None	Not recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	63	-826	52	No	Moderate	No	None	Recovered
	41093	56/Female	Digestive	DIARRHEA	DIARRHEA	72	-2	0	No	Moderate	No	None	Recovered
				GASTROESOPHAGEAL REFLUX	ACID REFLUX	72	-44	1	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Delgado	41093	56/Female	Nervous	APATHY	EMOTIONAL BLUNTING	72	-14	18	No	Moderate	No	None	Recovered
	41094	64/Female	Nervous	ANXIETY	ANXIETY	70	-28	46	No	Severe	Yes	None	Recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	70		24	No	Moderate	No	None	Recovered
DuBoff	311017	54/Male	Nervous	SOMNOLENCE	SEDATION	99	-94	7	No	Mild	No	None	Recovered
	311018	31/Female	Digestive	DRY MOUTH	DRY MOUTH	64		19	No	Mild	No	None	Recovered
			Nervous	INSOMNIA	INCREASED INSOMNIA	64		1	No	Severe	Yes	None	Recovered
Dunner	211040	53/Female	Cardiovascular	HYPERTENSION	ELEVATED BLOOD PRESSURE	79	-11		No	Mild	No	None	Not recovered
	211146	57/Male	Special Senses	TINNITUS	TINNITUS	57	-57	11	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Fava	51113	55/Female	Body	TRAUMA	RIB INJURY	58	-11	38	No	Mild	No	None	Recovered
	51141	30/Female	Nervous	HYPERTONIA	BODY SPASMS	58		18	No	Mild	No	None	Recovered
	51142	44/Female	Body	HEADACHE	HEADACHES	56	-126	1	No	Mild	No	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	56	-126		No	Moderate	Yes	None	Not recovered
			Nervous	HYPERTONIA	BODY SPASMS	56		1	No	Mild	No	None	Recovered
				INSOMNIA	INSOMNIA	56	-126	1	No	Mild	No	None	Recovered
				SOMNOLENCE	DROWSINESS	56	-126	1	No	Mild	No	None	Recovered
Ferguson	241031	61/Male	Body	HEADACHE	HEADACHES	3	-6	0	No	Moderate	Yes	None	Recovered
			Nervous	SOMNOLENCE	SEDATION	3	-93		No	Moderate	No	None	Not recovered
	241032	41/Female	Digestive	DRY MOUTH	DRY MOUTH	31		-1	No	Mild	No	None	Recovered
Helfing	81003	65/Female	Digestive	DRY MOUTH	DRY MOUTH	64	-19	0	No	Moderate	No	None	Recovered
	81052	39/Female	Digestive	DRY MOUTH	DRY MOUTH	20	-15	28	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Helfing	81076	23/Female	Body	GENERALIZED PAIN	BODY ACHES	171	-4	13	No	Moderate	No	None	Recovered
			Respiratory	PHARYNGITIS	STREP THROAT	171	-4	13	No	Moderate	No	None	Recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	171			No	Mild	No	None	Not recovered
Hoopes	271021	29/Male	Digestive	APPETITE DECREASED	DECREASED APPETITE	57	-14		No	Moderate	No	None	Not recovered
Liebowitz	91035	62/Female	Skin	DIAPHORETIC	INCREASED SWEATING OF FACE	57	-6		No	Mild	No	None	Not recovered
	91097	38/Female	Body	FATIGUE	FATIGUE	54	-44	26	No	Mild	No	None	Recovered
	91137	40/Male	Body	TRAUMA	10 STITCHES ON HEAD	57	-6	-6	No	Moderate	No	None	Recovered
					FALL	57	-6	-6	No	Moderate	No	None	Recovered
			Cardiovascular	VASODILATION	HOT FLASH	57	-6	-6	No	Moderate	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Liebowitz	91137	40/Male	Nervous	ATAXIA	LOSS OF BALANCE	57	-6	-6	No	Moderate	No	None	Recovered
	91138	45/Female	Body	UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	50	-5	11	No	Mild	No	None	Recovered
Londborg	101009	36/Female	Body	FATIGUE	DAYTIME FATIGUE	21	-185	2	No	Moderate	No	None	Recovered
	101010	51/Female	Nervous	CNS STIMULATION	CNS STIMULATION	57		17	No	Mild	No	Drug permanently withdrawn	Recovered
				LIBIDO DECREASED	DECREASED LIBIDO	57			No	Mild	No	Drug permanently withdrawn	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Londborg	101044	41/Female	Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	211		0	No	Moderate	No	None	Recovered
			Skin	DIAPHORETIC	NIGHT SWEATS	211		50	No	Moderate	No	None	Recovered
Lydiard	221034	40/Female	Body	FATIGUE	FATIGUE	42	-7		No	Moderate	Yes	None	Not recovered
				HEADACHE	HEADACHE	42	-5	-4	No	Moderate	No	None	Recovered
McGrath	111057	48/Male	Digestive	ERUCTATION	BELCHING	18	-36		No	Mild	No	None	Not recovered
				NAUSEA	NAUSEA	18	-36		No	Mild	No	None	Not recovered
Munjack	131011	56/Male	Body	REACTION UNEVALUABLE	TRIGGER FINGER CORRECTIVE SURGERY	198		156	No	Severe	No	None	Recovered
Rapaport	151037	62/Female	Digestive	VOMITING	VOMITTING	240		29	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Rapaport	151037	62/Female	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	240			No	Mild	No	None	Not recovered
	151038	52/Male	Digestive	DRY MOUTH	DRY MOUTH	141	-41	21	No	Mild	Yes	None	Recovered
			Nervous	PARESTHESIA	PARESTHESIA	141	-41	0	No	Mild	No	None	Recovered
				SOMNOLENCE	DROWSINESS	141	-41	42	No	Mild	No	None	Recovered
	151085	50/Female	Body	BACK PAIN	MUSCLE ACHE (BACK)	14	-2	13	No	Mild	No	None	Recovered
			Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	14			No	Mild	No	None	Not recovered
				SOMNOLENCE	DROWSINESS	14		7	No	Mild	No	None	Recovered
	151086	45/Female	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	38		2	No	Mild	No	None	Recovered
				SOMNOLENCE	DROWSINESS	38		21	No	Mild	No	None	Recovered
				TREMOR	SHAKING	38	-6	21	No	Mild	No	None	Recovered
	151095	49/Male	Skin	DIAPHORETIC	NIGHT SWEATS	156		0	No	Mild	No	None	Recovered
	151099	52/Female	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	77	-96	41	No	Mild	No	None	Recovered
				SOMNOLENCE	DROWSINESS	77		13	No	Mild	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Rapaport	151099	52/Female	Nervous	TREMOR	SHAKING	77	-96	8	No	Mild	No	None	Recovered
	151100	42/Female	Cardiovascular	TACHYCARDIA	RAPID HEART RATE	36		7	No	Mild	No	None	Recovered
			Digestive	DYSPEPSIA	HEARTBURN	36		34	No	Mild	Yes	None	Recovered
			Nervous	SOMNOLENCE	DROWSINESS	36	-75	1	No	Mild	Yes	None	Recovered
			Special Senses	BLURRED VISION	BLURRED VISION	36		34	No	Mild	Yes	None	Recovered
	151118	47/Male	Digestive	CONSTIPATION	CONSTIPATION	55	-86	28	No	Mild	Yes	None	Recovered
				DRY MOUTH	DRY MOUTH	55	-86	28	No	Mild	Yes	None	Recovered
			Urogenital	EJACULATION ABNORMAL	DELAYED EJACULATION	55	-86	28	No	Mild	Yes	None	Recovered
				URINATION IMPAIRED	URINARY HESITANCY	55	-86	28	No	Mild	Yes	None	Recovered
	151153	44/Male	Digestive	TOOTHACHE	TOOTH PAIN	20	-6	14	No	Mild	No	None	Recovered
Thase	181083	58/Male	Digestive	LOOSE STOOLS NEC	VERY LOOSE BOWEL MOVEMENT	143	-5	-1	No	Moderate	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Thase	181084	32/Male	Digestive	DYSPEPSIA	HEARTBURN	120	-2	-1	No	Mild	No	None	Recovered
			Respiratory	SINUSITIS	SINUS PAIN	120	-3	23	No	Mild	No	None	Recovered
					SINUS PRESSURE	120	-3	23	No	Mild	No	None	Recovered
	181105	37/Female	Nervous	NIGHTMARES	NIGHTMARES	56	-7	-1	No	Moderate	No	None	Recovered
Trivedi	191013	36/Female	Body	HEADACHE	HEADACHE	44	-2	-2	No	Moderate	No	None	Recovered
Walsh	171015	45/Female	Body	HEADACHE	HEADACHE	85	-10	-10	No	Mild	No	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	85	-29		No	Mild	No	None	Not recovered
	171062	52/Female	Nervous	INSOMNIA	INSOMNIA	64	-72	40	No	Moderate	No	None	Recovered
	171063	27/Male	Body	ASTHENIA	FEELING TIRED	88	-869	11	No	Moderate	No	None	Recovered
			Nervous	LIBIDO DECREASED	LOSS OF SEX DRIVE	88	-869	61	No	Moderate	No	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events That Started before Treatment
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Days on Study Med.	Onset Day	Stop Day	Serious	Max. Intensity	Rel. to Study Med.	Action Taken	Outcome
Zajecka	201068	37/Female	Digestive	LIVER FUNCTION TESTS ABNORMAL NOS	ELEVATED LIVER ENZYMES	94	-11	77	No	Mild	No	None	Recovered
	201091	34/Female	Body	TRAUMA	MUSCLE STRAIN UNDER LEFT BREAST	8	-7		No	Severe	No	None	Not recovered
			Nervous	LIBIDO DECREASED	DECREASED LIBIDO	8			No	Moderate	No	None	Not recovered
	201092	41/Female	Nervous	INSOMNIA	INSOMNIA	24	-41	31	No	Moderate	No	None	Recovered
					SLEEPLESSNESS	24	-41	31	No	Mild	No	None	Recovered
	201123	43/Female	Body	ASTHENIA	TIREDNESS	56	-28		No	Mild	No	None	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Frequencies of Treatment Emergent Adverse Events Reported in the Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Study Period	No. of AEs	No. of Patients
Before Day 1	5	5
Week 1	453	117
Week 2	144	72
Week 3	100	49
Week 4	87	47
Week 5	81	46
Week 6	67	34
Week 7	51	31
Week 8	33	22
Others before blinded phase	9	7

Notes: 1. The number of weeks here is calculated based on the number of days from baseline. It might not coincide with the visit week reported on the CRFs, as some patients might have delayed or early visits.
2. A few adverse events that started before Day 1 but had increased in intensity after day 1 are included here.

Table AE5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System
All Enrolled Patients

Date Produced: January 15, 2001

Body System	--- Patients --- (N=128)		# of Reports
	n	%	
No of AE reported			1030
Patients with at least one AE	125	97.7	
Body	97	75.8	291
Cardiovascular	39	30.5	54
Digestive	95	74.2	226
Hemic and Lymphatic	1	0.8	1
Metabolic and Nutritional	8	6.3	9
Musculo-Skeletal	12	9.4	18
Nervous	99	77.3	240
Respiratory	23	18.0	34
Skin	43	33.6	64

(CONTINUED)

Table AE5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System
All Enrolled Patients

Date Produced: January 15, 2001

Body System	--- Patients --- (N=128)		# of Reports
	n	%	
Special Senses	23	18.0	25
Urogenital	40	31.3	68

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				1030
Patients with at least one AE		125	97.7	
Body	ABDOMINAL CRAMP	7	5.5	8
	ABDOMINAL DISTENSION	7	5.5	7
	ABDOMINAL PAIN GENERALIZED	1	0.8	2
	ABDOMINAL PAIN LOCALIZED	2	1.6	2
	ALLERGIC REACTION	4	3.1	4
	ASTHENIA	6	4.7	6
	BACK PAIN	16	12.5	18
	CHEST PAIN	5	3.9	7

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	CHILLS	18	14.1	22
	ENVIRONMENTAL ALLERGY	3	2.3	4
	FATIGUE	7	5.5	17
	FEVER	2	1.6	2
	FLU SYNDROME	7	5.5	7
	GENERALIZED EDEMA	4	3.1	4
	GENERALIZED PAIN	1	0.8	2
	HANGOVER	1	0.8	1
	HEADACHE	61	47.7	107
	INFECTION FUNGAL NOS	1	0.8	1
	LOCALIZED EDEMA	1	0.8	1

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	LOCALIZED PAIN	12	9.4	12
	NECK PAIN	3	2.3	5
	NECK RIGID	1	0.8	1
	NON-GENERALIZED WEAKNESS NOS	2	1.6	4
	REACTION UNEVALUABLE	9	7.0	13
	SUICIDE ATTEMPT	1	0.8	1
	TRAUMA	12	9.4	14
	UPPER RESPIRATORY INFECTION	17	13.3	19
Cardiovascular	DISORDER PERIPHERAL VASCULAR	3	2.3	4
	HYPERTENSION	2	1.6	2

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Cardiovascular	HYPOTENSION	1	0.8	1
	HYPOTENSION POSTURAL	4	3.1	4
	MIGRAINE	3	2.3	3
	PALPITATION	8	6.3	8
	SINUS TACHYCARDIA	1	0.8	1
	TACHYCARDIA	5	3.9	5
	VASODILATION	20	15.6	26
Digestive	APPETITE DECREASED	15	11.7	15
	APPETITE INCREASED	3	2.3	8
	CONSTIPATION	36	28.1	40
	DIARRHEA	8	6.3	8

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	DISORDER RECTAL	1	0.8	1
	DISORDER TONGUE	1	0.8	2
	DRY MOUTH	56	43.8	65
	DYSPEPSIA	19	14.8	24
	FLATULENCE	4	3.1	4
	GASTRITIS	1	0.8	1
	GASTROENTERITIS	3	2.3	3
	GASTROINTESTINAL BLEEDING	1	0.8	1
	GINGIVITIS	1	0.8	1
	HEMORRHOID	2	1.6	2
	INCREASED THIRST	2	1.6	2

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	LOOSE STOOLS NEC	2	1.6	2
	NAUSEA	26	20.3	36
	RECTAL BLEEDING	1	0.8	1
	STOMATITIS APHTHOUS	1	0.8	1
	THROAT DRY	1	0.8	1
	TOOTH ABSCESS	1	0.8	1
	TOOTHACHE	2	1.6	2
	ULCER MOUTH	1	0.8	1
	VOMITING	4	3.1	4
Hemic and Lymphatic	ECCHYMOSIS/BRUISE	1	0.8	1
Metabolic and Nutritional	BILIRUBINEMIA	1	0.8	1

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Metabolic and Nutritional	HYPERCHOLESTEREMIA	1	0.8	1
	PERIPHERAL EDEMA	3	2.3	3
	WEIGHT DECREASE	1	0.8	1
	WEIGHT INCREASE	2	1.6	3
Musculo-Skeletal	CARPAL TUNNEL SYNDROME	1	0.8	1
	CRAMP LEGS	6	4.7	8
	JOINT STIFFNESS	1	0.8	1
	MUSCULAR WEAKNESS	1	0.8	2
	MYALGIA	6	4.7	6
Nervous	AGITATION	3	2.3	4
	AKATHISIA	1	0.8	1

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	AMNESIA	1	0.8	2
	ANXIETY	14	10.9	16
	ATAXIA	1	0.8	1
	CHANGE IN DREAMS	8	6.3	10
	CNS STIMULATION	1	0.8	1
	CONCENTRATION IMPAIRED	4	3.1	4
	CONFUSION	2	1.6	2
	DEPRESSIVE SYMPTOMS	3	2.3	3
	DIZZINESS	32	25.0	47
	DRUG DEPENDENCE	1	0.8	1
	EMOTIONAL LABILITY	1	0.8	1

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	HOSTILITY	1	0.8	1
	HYPERTONIA	4	3.1	4
	HYPESTHESIA	1	0.8	2
	INSOMNIA	61	47.7	71
	LIBIDO DECREASED	2	1.6	2
	MANIC SYMPTOMS	3	2.3	3
	MUSCLE CRAMP	2	1.6	4
	NERVOUSNESS	13	10.2	13
	NIGHTMARES	3	2.3	3
	PARASOMNIA NOS	1	0.8	1
	PARESTHESIA	11	8.6	15

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	RESTLESSNESS	2	1.6	2
	SCIATICA NOS	1	0.8	1
	SOMNILOQUISM	1	0.8	1
	SOMNOLENCE	14	10.9	19
	SUICIDAL TENDENCY	2	1.6	2
	TREMOR	3	2.3	3
Respiratory	ASTHMA	1	0.8	1
	BRONCHITIS	3	2.3	4
	CONGESTION CHEST	1	0.8	1
	COUGH	1	0.8	1
	DYSPNEA	2	1.6	2

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Respiratory	EPISTAXIS	1	0.8	1
	PHARYNGITIS	4	3.1	4
	RHINITIS	7	5.5	12
	SINUSITIS	8	6.3	8
Skin	DERMATITIS	1	0.8	1
	DIAPHORETIC	34	26.6	41
	DISORDER HAIR	1	0.8	1
	DISORDER SKIN NEC	1	0.8	1
	DRY SKIN NON-APPLICATION SITE	1	0.8	1
	ECZEMA	1	0.8	1
	ERYTHEMA	1	0.8	2

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Skin	HAIR LOSS	1	0.8	1
	HERPES SIMPLEX DERM	2	1.6	2
	NODULE SKIN	1	0.8	1
	PRURITUS NON-APPLICATION SITE	2	1.6	5
	RASH	5	3.9	6
	SKIN EROSION NEC	1	0.8	1
Special Senses	BLURRED VISION	6	4.7	6
	DISORDER EYE	1	0.8	1
	DISORDER LACRIMATION	1	0.8	1
	DRY EYES	1	0.8	1
	EAR PAIN	1	0.8	1

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Special Senses	EYE IRRITATION	1	0.8	1
	EYE PAIN	1	0.8	1
	TASTE PERVERSION	8	6.3	8
	TINNITUS	5	3.9	5
Urogenital	BREAST PAIN	1	0.8	1
	DISORDER MENSTRUAL NEC	2	1.6	2
	DISORDER TESTICLE	2	1.6	2
	DISORDER URETHRAL	1	0.8	1
	DISORDER VULVOVAGINAL	2	1.6	2
	DYSMENORRHEA	1	0.8	1
	DYSURIA	4	3.1	5

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	EJACULATION ABNORMAL	9	7.0	10
	FREQUENCY URINARY	1	0.8	1
	IMPOTENCE	7	5.5	7
	INFECTION URINARY TRACT	3	2.3	3
	MENOPAUSE	1	0.8	1
	NOCTURIA	1	0.8	1
	OLIGURIA	1	0.8	1
	PAIN TESTICULAR	1	0.8	1
	POLYURIA	1	0.8	1
	PYELONEPHRITIS	1	0.8	1
	RETENTION URINARY	5	3.9	6

(CONTINUED)

Table AE6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	SEXUAL FUNCTION ABNORMAL	2	1.6	2
	URGENCY URINATION	2	1.6	2
	URINATION IMPAIRED	17	13.3	17

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				648
Patients with at least one AE		118	92.2	
Body	ABDOMINAL CRAMP	5	3.9	5
	ABDOMINAL DISTENSION	2	1.6	2
	ABDOMINAL PAIN LOCALIZED	1	0.8	1
	ASTHENIA	5	3.9	5
	CHEST PAIN	1	0.8	2
	CHILLS	14	10.9	17
	FATIGUE	2	1.6	2
	FEVER	1	0.8	1
	GENERALIZED EDEMA	2	1.6	2

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	HEADACHE	43	33.6	69
	LOCALIZED PAIN	2	1.6	2
	NECK PAIN	1	0.8	1
	NON-GENERALIZED WEAKNESS NOS	1	0.8	3
	REACTION UNEVALUABLE	5	3.9	5
	SUICIDE ATTEMPT	1	0.8	1
Cardiovascular	DISORDER PERIPHERAL VASCULAR	2	1.6	3
	HYPERTENSION	1	0.8	1
	HYPOTENSION POSTURAL	3	2.3	3
	PALPITATION	7	5.5	7

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Cardiovascular	TACHYCARDIA	4	3.1	4
	VASODILATION	18	14.1	24
Digestive	APPETITE DECREASED	15	11.7	15
	APPETITE INCREASED	2	1.6	7
	CONSTIPATION	33	25.8	35
	DIARRHEA	4	3.1	4
	DRY MOUTH	56	43.8	64
	DYSPEPSIA	12	9.4	13
	FLATULENCE	1	0.8	1
	GASTROENTERITIS	1	0.8	1
	HEMORRHOID	1	0.8	1

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	INCREASED THIRST	2	1.6	2
	LOOSE STOOLS NEC	1	0.8	1
	NAUSEA	21	16.4	28
	THROAT DRY	1	0.8	1
	ULCER MOUTH	1	0.8	1
	VOMITING	3	2.3	3
Metabolic and Nutritional	BILIRUBINEMIA	1	0.8	1
	PERIPHERAL EDEMA	1	0.8	1
	WEIGHT INCREASE	2	1.6	2
Musculo-Skeletal	MYALGIA	1	0.8	1
Nervous	AGITATION	3	2.3	4

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	ANXIETY	12	9.4	12
	ATAXIA	1	0.8	1
	CHANGE IN DREAMS	8	6.3	10
	CNS STIMULATION	1	0.8	1
	CONCENTRATION IMPAIRED	2	1.6	2
	CONFUSION	2	1.6	2
	DEPRESSIVE SYMPTOMS	2	1.6	2
	DIZZINESS	28	21.9	40
	EMOTIONAL LABILITY	1	0.8	1
	HOSTILITY	1	0.8	1
	HYPERTONIA	1	0.8	1

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	INSOMNIA	50	39.1	57
	LIBIDO DECREASED	2	1.6	2
	MANIC SYMPTOMS	3	2.3	3
	NERVOUSNESS	11	8.6	11
	NIGHTMARES	3	2.3	3
	PARESTHESIA	9	7.0	13
	RESTLESSNESS	2	1.6	2
	SOMNILOQUISM	1	0.8	1
	SOMNOLENCE	12	9.4	17
	TREMOR	2	1.6	2
Respiratory	DYSPNEA	1	0.8	1

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Respiratory	RHINITIS	2	1.6	2
Skin	DERMATITIS	1	0.8	1
	DIAPHORETIC	30	23.4	34
	DISORDER HAIR	1	0.8	1
	DISORDER SKIN NEC	1	0.8	1
	ECZEMA	1	0.8	1
	ERYTHEMA	1	0.8	2
	HAIR LOSS	1	0.8	1
	PRURITUS NON-APPLICATION SITE	2	1.6	5
	RASH	2	1.6	2
Special Senses	BLURRED VISION	5	3.9	5

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Special Senses	DRY EYES	1	0.8	1
	EYE IRRITATION	1	0.8	1
	EYE PAIN	1	0.8	1
	TASTE PERVERSION	8	6.3	8
	TINNITUS	4	3.1	4
Urogenital	DISORDER MENSTRUAL NEC	1	0.8	1
	DISORDER TESTICLE	1	0.8	1
	DYSURIA	2	1.6	2
	EJACULATION ABNORMAL	9	7.0	10
	IMPOTENCE	6	4.7	6
	MENOPAUSE	1	0.8	1

(CONTINUED)

Table AE7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Considered Related to Study Medication - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	NOCTURIA	1	0.8	1
	OLIGURIA	1	0.8	1
	PAIN TESTICULAR	1	0.8	1
	POLYURIA	1	0.8	1
	RETENTION URINARY	5	3.9	6
	SEXUAL FUNCTION ABNORMAL	2	1.6	2
	URINATION IMPAIRED	14	10.9	14

Table AE8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Resulted in Early Termination - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				54
Patients with at least one AE		21	16.4	
Body	ABDOMINAL CRAMP	2	1.6	2
	CHILLS	2	1.6	2
	GENERALIZED EDEMA	1	0.8	1
	REACTION UNEVALUABLE	1	0.8	1
	SUICIDE ATTEMPT	1	0.8	1
Cardiovascular	HYPOTENSION POSTURAL	1	0.8	1
	VASODILATION	2	1.6	2
Digestive	APPETITE DECREASED	1	0.8	1
	CONSTIPATION	4	3.1	4

(CONTINUED)

Table AE8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Resulted in Early Termination - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	DIARRHEA	1	0.8	1
	NAUSEA	2	1.6	2
Nervous	AGITATION	1	0.8	1
	ANXIETY	2	1.6	2
	ATAXIA	1	0.8	1
	CONFUSION	1	0.8	1
	DEPRESSIVE SYMPTOMS	1	0.8	1
	DIZZINESS	2	1.6	2
	HOSTILITY	1	0.8	1
	INSOMNIA	8	6.3	8
	MANIC SYMPTOMS	2	1.6	2

(CONTINUED)

Table AE8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Resulted in Early Termination - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	NERVOUSNESS	1	0.8	1
	NIGHTMARES	1	0.8	1
	SOMNOLENCE	1	0.8	1
	SUICIDAL TENDENCY	1	0.8	1
Skin	DIAPHORETIC	2	1.6	2
	ECZEMA	1	0.8	1
	HAIR LOSS	1	0.8	1
Special Senses	BLURRED VISION	1	0.8	1
	TASTE PERVERSION	1	0.8	1
Urogenital	DISORDER TESTICLE	1	0.8	1
	EJACULATION ABNORMAL	3	2.3	3

(CONTINUED)

Table AE8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Resulted in Early Termination - Frequency by Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	IMPOTENCE	1	0.8	1
	URINATION IMPAIRED	2	1.6	2

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Amsterdam	11065	59/Male	Digestive	DRY MOUTH	DRY MOUTH	1	13	44	No	Mild	None	Recovered
			Urogenital	IMPOTENCE	IMPOTENCE	1		44	No	Moderate	None	Not recovered
	11066	56/Male	Body	CHILLS	COLD SENSATION IN FINGERTIPS	0		80	No	Mild	None	Not recovered
			Nervous	INSOMNIA	MIDDLE INSOMNIA	57		80	No	Moderate	None	Not recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	15		80	No	Moderate	None	Not recovered
	11133	41/Male	Body	FEVER	FEVER	17	3	64	No	Moderate	Drug temporarily withdrawn	Recovered
	11134	49/Male	Urogenital	EJACULATION ABNORMAL	PREMATURE EJACULATION	31		60	No	Mild	None	Not recovered
	11159	48/Female	Digestive	NAUSEA	NAUSEA (INTERMITTENT)	16		58	No	Mild	None	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Amsterdam	11160	61/Male	Digestive	CONSTIPATION	CONSTIPATION	6		56	No	Moderate	None	Not recovered
			Nervous	ANXIETY	JITTERINESS	1	12	56	No	Moderate	None	Recovered
Barbee	21053	30/Male	Body	HEADACHE	HEADACHE	47	1	50	No	Moderate	None	Recovered
			Digestive	DRY MOUTH	INCREASED DRY MOUTH	12		50	No	Mild	None	Not recovered
				DYSPEPSIA	HEARTBURN	25	10	50	No	Moderate	None	Recovered
						48	1	50	No	Moderate	None	Recovered
				NAUSEA	NAUSEA	25	3	50	No	Mild	None	Recovered
			Nervous	EMOTIONAL LABILITY	MOOD LABILITY	37		50	No	Mild	None	Not recovered
				NERVOUSNESS	IRRITABILITY	21		50	No	Moderate	None	Not recovered
			Special Senses	TASTE PERVERSION	METALLIC TASTE	25		50	No	Mild	None	Not recovered
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	2		50	No	Mild	None	Not recovered
Clayton	31019	45/Male	Digestive	DYSPEPSIA	ACID INDIGESTION	2	5	85	No	Severe	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Clayton	31111	37/Female	Digestive	NAUSEA	NAUSEA	15	3	19	No	Mild	None	Recovered
				VOMITING	VOMITING	17	1	19	No	Mild	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	15	3	19	No	Mild	None	Recovered
					LIGHTHEADEDNESS	15	3	19	No	Mild	None	Recovered
	31112	44/Female	Cardiovascular	PALPITATION	HEART RACING	0	1	60	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	1	29	60	No	Mild	None	Recovered
				NAUSEA	NAUSEA	0	1	60	No	Mild	None	Recovered
Croft	231001	50/Female	Digestive	DRY MOUTH	DRY MOUTH	9		128	No	Mild	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	0		128	No	Severe	None	Not recovered
			Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	9		128	No	Mild	None	Not recovered
	231002	40/Female	Nervous	INSOMNIA	INSOMNIA	0	11	28	No	Severe	None	Recovered
	231079	65/Male	Digestive	DRY MOUTH	DRY MOUTH	2	38	136	No	Moderate	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	2	42	136	No	Mild	None	Recovered
						53	4	136	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Croft	231079	65/Male	Urogenital	RETENTION URINARY	URINE RETENTION	0	43	136	No	Moderate	None	Recovered
						53	4	136	No	Mild	None	Recovered
	231080	55/Female	Body	ABDOMINAL CRAMP	STOMACH CRAMPS	8		50	No	Mild	None	Not recovered
				HEADACHE	HEADACHES	13		50	No	Moderate	None	Not recovered
			Cardiovascular	VASODILATION	NIGHTLY HOT FLASHES	11		50	No	Mild	None	Not recovered
			Digestive	DIARRHEA	DIARRHEA	8	28	50	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	0	37	50	No	Mild	None	Recovered
			Nervous	ANXIETY	JITTERINESS IN LATE AFTERNOON	2	14	50	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	0		50	No	Moderate	None	Not recovered
			Special Senses	TASTE PERVERSION	STRANGE TASTE IN MOUTH	9	34	50	No	Moderate	None	Recovered
			Urogenital	RETENTION URINARY	URINE RETENTION	22		50	No	Moderate	None	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Croft	231119	56/Female	Body	ABDOMINAL DISTENSION	ABDOMINAL BLOATING	38		75	No	Mild	None	Not recovered
			Digestive	APPETITE DECREASED	DECREASED APPETITE	32		75	No	Moderate	None	Not recovered
				FLATULENCE	FLATULENCE	1	25	75	No	Mild	None	Recovered
				LOOSE STOOLS NEC	LOOSE STOOLS	1	14	75	No	Mild	None	Recovered
				THROAT DRY	DRY THROAT	1		75	No	Mild	None	Not recovered
			Nervous	ANXIETY	ANXIETY	34		75	No	Moderate	None	Not recovered
				CHANGE IN DREAMS	VIVID DREAMS	3		75	No	Mild	None	Not recovered
				DIZZINESS	DIZZINESS	35	1	75	No	Mild	None	Recovered
				NERVOUSNESS	IRRITABILITY	14		75	No	Moderate	None	Not recovered
			Skin	DIAPHORETIC	INCREASED PERSPIRATION	33	16	75	No	Moderate	None	Recovered
					NIGHT SWEATS	9	19	75	No	Moderate	None	Recovered
			Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	39		75	No	Mild	None	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Croft	231120	54/Female	Nervous	CHANGE IN DREAMS	VIVID DREAMS	10	3	68	No	Mild	None	Recovered
				NERVOUSNESS	IRRITABILITY	3	1	68	No	Mild	None	Recovered
	231139	36/Female	Body	ABDOMINAL CRAMP	INTESTINAL CRAMPING	33	1	59	No	Moderate	None	Recovered
				FATIGUE	FATIGUE	14	30	59	No	Moderate	None	Recovered
				HEADACHE	INCREASED FREQUENCY HEADACHE	15	9	59	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	34	2	59	No	Moderate	None	Recovered
				DRY MOUTH	DRY MOUTH	10	34	59	No	Moderate	None	Recovered
				NAUSEA	NAUSEA	35	1	59	No	Moderate	None	Recovered
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	8		59	No	Moderate	None	Not recovered
Delgado	41069	41/Female	Digestive	CONSTIPATION	CONSTIPATION	15	8	71	No	Moderate	None	Recovered
			Nervous	ANXIETY	ANXIETY	1		71	No	Moderate	None	Not recovered
				HYPERTONIA	MUSCLE TENSION	15		71	No	Mild	None	Not recovered
				NERVOUSNESS	IRRITABILITY	1	51	71	No	Severe	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Delgado	41069	41/Female	Skin	ERYTHEMA	2 REDDENED PATCHES OF SKIN ON LEFT LOWER EXTREMITY	57		71	No	Mild	None	Not recovered
					3 REDDENED PATCHES OF SKIN RIGHT LOWER EXTREMITY	57		71	No	Mild	None	Not recovered
	41070	46/Female	Body	CHILLS	COLD SENSATIONS	1	1	63	No	Mild	None	Recovered
						4	1	63	No	Mild	None	Recovered
						6	1	63	No	Mild	None	Recovered
				HEADACHE	HEADACHE	30	2	63	No	Moderate	None	Recovered
						46	1	63	No	Moderate	None	Recovered
					HEADACHES	2	1	63	No	Moderate	None	Recovered
						4	1	63	No	Moderate	None	Recovered
						20	2	63	No	Moderate	None	Recovered
						54	1	63	No	Moderate	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Delgado	41070	46/Female	Body	NON-GENERALIZED WEAKNESS NOS	SENSATION OF WEAKNESS IN ARMS	55	1	63	No	Mild	None	Recovered
					WEAKNESS IN LEGS	4	1	63	No	Mild	None	Recovered
						55	1	63	No	Mild	None	Recovered
				REACTION UNEVALUABLE	SENSATION OF HEAVINESS IN LEGS	10	2	63	No	Mild	None	Recovered
			Cardiovascular	PALPITATION	PALPITATIONS	15	3	63	No	Moderate	None	Recovered
				VASODILATION	HOT FLASHES	1	2	63	No	Mild	None	Recovered
						4	1	63	No	Mild	None	Recovered
						6	1	63	No	Mild	None	Recovered
						12	1	63	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	6	9	63	No	Moderate	None	Recovered
				DRY MOUTH	DRY MOUTH			63	No	Severe	None	Not recovered
				GASTROENTERITIS	GASTROENTERITIS	45	1	63	No	Mild	None	Recovered
				NAUSEA	NAUSEA	0	1	63	No	Mild	None	Recovered
						19	1	63	No	Mild	None	Recovered
				ULCER MOUTH	SORES IN ROOF OF MOUTH	4	5	63	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Delgado	41070	46/Female	Nervous	CHANGE IN DREAMS	VIVID DREAMS	10	1	63	No	Mild	None	Recovered
						25	1	63	No	Mild	None	Recovered
						43	1	63	No	Mild	None	Recovered
				PARESTHESIA	TINGLING SENSATION IN LEFT ARM	34	1	63	No	Mild	None	Recovered
					TINGLING SENSATION IN SCALP	0	1	63	No	Mild	None	Recovered
			Skin	PRURITUS NON-APPLICATION SITE	ITCHY SCALP	0	3	63	No	Mild	None	Recovered
						4	1	63	No	Mild	None	Recovered
						9	1	63	No	Mild	None	Recovered
						12	1	63	No	Mild	None	Recovered
			Special Senses	BLURRED VISION	BLURRED VISION	0		63	No	Moderate	None	Not recovered
	41093	56/Female	Body	REACTION UNEVALUABLE	SENSATION OF HEAVINESS IN LEGS	56	1	72	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	2	5	72	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Delgado	41093	56/Female	Digestive	DRY MOUTH	DRY MOUTH	44	1	72	No	Mild	None	Recovered
			Nervous	CONFUSION	CONFUSION	56	1	72	No	Moderate	None	Recovered
			Skin	PRURITUS NON-APPLICATION SITE	ITCHY MOUTH	28	1	72	No	Mild	None	Recovered
	41094	64/Female	Digestive	DYSPEPSIA	HEARTBURN	8	1	70	No	Mild	None	Recovered
DuBoff	311018	31/Female	Nervous	INSOMNIA	INCREASED INSOMNIA			64	No	Severe	None	Recovered
	311115	30/Female	Body	CHILLS	COLD FLASHES	1	2	113	No	Mild	Dose reduced	Recovered
			Cardiovascular	VASODILATION	HOT FLASHES	1	2	113	No	Mild	Dose reduced	Recovered
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	1	44	113	No	Mild	None	Recovered
				DIARRHEA	DIARRHEA	11	1	113	No	Mild	None	Recovered
				INCREASED THIRST	POLYDYPSIA	7	45	113	No	Moderate	None	Recovered
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	22	36	113	No	Moderate	None	Recovered
				DIZZINESS	DIZZINESS	1	1	113	No	Moderate	Dose reduced	Recovered
						26	19	113	No	Moderate	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
DuBoff	311115	30/Female	Nervous	PARESTHESIA	PARESTHESIA TOP OF HEAD	1	14	113	No	Mild	Dose reduced	Recovered
				TREMOR	TREMULOUSNESS	1	72	113	No	Mild	None	Recovered
	311116	44/Female	Urogenital	MENOPAUSE	PREMENOPAUSAL SYMPTOMS	1	6		No	Moderate	None	Recovered
Dunner	211039	53/Female	Body	HEADACHE	HEADACHE	15	2	60	No	Moderate	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	2	33	60	No	Moderate	None	Recovered
				DYSPEPSIA	HEARTBURN	29	16	60	No	Mild	None	Recovered
			Nervous	INSOMNIA	WORSE INSOMNIA	1		60	No	Moderate	None	Not recovered
	211040	53/Female	Nervous	DIZZINESS	BRIEF DIZZINESS	23	27	79	No	Mild	None	Recovered
	211109	43/Male	Cardiovascular	HYPOTENSION POSTURAL	OCCASIONAL SYMPTOMS OF ORTHOSTATIC HYPOTENSION/DIZZINESS ON STANDING	4	33	78	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Dunner	211109	43/Male	Cardiovascular	PALPITATION	PALPITATIONS	2	30	78	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	0	73	78	No	Mild	None	Recovered
				DYSPEPSIA	INDIGESTION	0		78	No	Moderate	None	Not recovered
			Skin	DIAPHORETIC	NIGHT SWEATS	2	55	78	No	Mild	None	Recovered
	211110	54/Female	Body	HEADACHE	HEADACHE	3	2	78	No	Moderate	None	Recovered
			Digestive	APPETITE DECREASED	DECREASED APPETITE	0	9	78	No	Mild	None	Recovered
				NAUSEA	AM NAUSEA	29	1	78	No	Mild	None	Recovered
					NAUSEA	0	5	78	No	Severe	Dose reduced	Recovered
			Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	53	18	78	No	Mild	None	Recovered
			Nervous	DIZZINESS	LIGHT HEADEDNESS	0	5	78	No	Severe	Dose reduced	Recovered
						16	1	78	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	29	4	78	No	Mild	None	Recovered
						44	21	78	No	Mild	None	Recovered
				SOMNOLENCE	SEDATION	0	5	78	No	Severe	Dose reduced	Recovered
			Skin	DIAPHORETIC	NIGHT SWEATS	0	60	78	No	Mild	None	Recovered
	211145	41/Male	Cardiovascular	PALPITATION	HEART RACING	1	8	46	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Dunner	211145	41/Male	Digestive	DRY MOUTH	DRY MOUTH	1		46	No	Mild	None	Not recovered
				DYSPEPSIA	HEARTBURN	1	8	46	No	Moderate	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	1		46	No	Moderate	None	Not recovered
				LIBIDO DECREASED	DECREASED LIBIDO	1		46	No	Moderate	None	Not recovered
				SOMNOLENCE	DAYTIME SLEEPINESS	1		46	No	Moderate	None	Not recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	1		46	No	Mild	None	Not recovered
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	9		46	No	Moderate	None	Not recovered
	211146	57/Male	Body	CHILLS	CHILLS	1		57	No	Mild	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	1		57	No	Moderate	None	Not recovered
			Nervous	INSOMNIA	WORSE INSOMNIA	1	3	57	No	Mild	None	Recovered
			Urogenital	EJACULATION ABNORMAL	PREMATURE EJACULATION	16	32	57	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Dunner	211146	57/Male	Urogenital	IMPOTENCE	IMPOTENCE	36		57	No	Moderate	None	Not recovered
				URINATION IMPAIRED	DIFFICULTY URINATING	2	10	57	No	Mild	None	Recovered
	211147	37/Female	Body	HEADACHE	HEADACHE	2		8	No	Mild	None	Not recovered
				SUICIDE ATTEMPT	SUICIDE ATTEMPT	7	8	8	Yes	Severe	Drug permanently withdrawn	Recovered
			Nervous	ANXIETY	ANXIETY ATTACK	1	1	8	No	Moderate	None	Recovered
				DIZZINESS	LIGHTHEADED	3		8	No	Mild	None	Not recovered
				INSOMNIA	INSOMNIA	2	2	8	No	Mild	None	Recovered
Fava	51113	55/Female	Digestive	DRY MOUTH	DRY MOUTH	4		58	No	Mild	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	4	26	58	No	Mild	None	Recovered
	51141	30/Female	Body	REACTION UNEVALUABLE	TEMPERATURE SENSITIVITY	0	7	58	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Fava	51141	30/Female	Nervous	NIGHTMARES	NIGHTMARES	7		58	No	Moderate	None	Not recovered
	51142	44/Female	Digestive	DRY MOUTH	DRY MOUTH	-126		56	No	Moderate	None	Not recovered
Ferguson	241031	61/Male	Body	ABDOMINAL CRAMP	STOMACH CRAMPS	1	3	3	No	Moderate	Drug permanently withdrawn	Recovered
				REACTION UNEVALUABLE	HEAVY STOMACH	0	4	3	No	Mild	Drug permanently withdrawn	Recovered
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	1	3	3	No	Mild	Drug permanently withdrawn	Recovered
				CONSTIPATION	CONSTIPATION	1	3	3	No	Mild	Drug permanently withdrawn	Recovered
				NAUSEA	NAUSEA	0	4	3	No	Mild	Drug permanently withdrawn	Recovered

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Ferguson	241031	61/Male	Nervous	CONFUSION	CONFUSION	0	4	3	No	Mild	Drug permanently withdrawn	Recovered
				INSOMNIA	INSOMNIA	0	4	3	No	Mild	Drug permanently withdrawn	Recovered
	241032	41/Female	Nervous	DIZZINESS	LIGHT HEADED	8	1	31	No	Mild	None	Recovered
						14	1	31	No	Mild	None	Recovered
	241073	26/Female	Body	CHILLS	COLD CHILLS	2	4	42	No	Mild	None	Recovered
			Cardiovascular	VASODILATION	HOT FLASHES	21		42	No	Mild	None	Not recovered
			Nervous	DIZZINESS	LIGHT HEADED	2		42	No	Mild	None	Not recovered
				NERVOUSNESS	INCREASED IRRITABILITY	36		42	No	Mild	None	Not recovered
	241074	21/Female	Body	HEADACHE	INCREASED SEVERITY OF HEADACHES	20		42	No	Moderate	None	Not recovered
			Cardiovascular	TACHYCARDIA	INCREASED HEART RATE	1	8	42	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Ferguson	241074	21/Female	Digestive	DRY MOUTH	DRY MOUTH	1	13	42	No	Mild	None	Recovered
						30	3	42	No	Mild	None	Recovered with sequelae
			Nervous	INSOMNIA	INSOMNIA	1	18	42	No	Moderate	None	Recovered
Gilmer	61081	45/Female	Body	CHILLS	CHILLS	0	7	5	No	Mild	Drug permanently withdrawn	Recovered
			Cardiovascular	VASODILATION	FEELING FLUSHED	0	7	5	No	Mild	Drug permanently withdrawn	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	0		5	No	Mild	Drug permanently withdrawn	Not recovered
			Nervous	ATAXIA	ATAXIA	7		5	No	Mild	Drug permanently withdrawn	Not recovered
				DIZZINESS	DIZZINESS	0		5	No	Severe	Drug permanently withdrawn	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Gilmer	61081	45/Female	Nervous	SOMNOLENCE	DROWSINESS	0	7	5	No	Severe	Drug permanently withdrawn	Recovered
	61082	56/Female	Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPS	2		6	No	Moderate	Drug permanently withdrawn	Not recovered
				CHILLS	CHILLS	2		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Digestive	NAUSEA	NAUSEA	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Nervous	INSOMNIA	INSOMNIA	0		6	No	Moderate	Drug permanently withdrawn	Not recovered
				MANIC SYMPTOMS	RACING THOUGHTS	3		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Skin	DIAPHORETIC	SWEATING	0		6	No	Moderate	Drug permanently withdrawn	Not recovered

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Halbreich	71077	56/Female	Body	HEADACHE	HEADACHE	14	1	64	No	Moderate	None	Recovered
			Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD HANDS	2		64	No	Moderate	None	Not recovered
			Digestive	APPETITE DECREASED	DECREASED APPETITE	2	40	64	No	Moderate	None	Recovered
				CONSTIPATION	CONSTIPATION	2		64	No	Moderate	None	Not recovered
				DRY MOUTH	DRY MOUTH	2		64	No	Moderate	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	2		64	No	Moderate	None	Not recovered
				NIGHTMARES	VIOLENT DREAMS	61		64	No	Moderate	Drug permanently withdrawn	Not recovered
Helfing	81003	65/Female	Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPING	39		64	No	Moderate	None	Not recovered
				HEADACHE	TENSION HEADACHE	29	26	64	No	Moderate	None	Recovered
			Digestive	APPETITE DECREASED	EARLY SATIETY	4		64	No	Mild	None	Not recovered

Note: Onset day and stop day are relative to Baseline

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Helfing	81003	65/Female	Digestive	CONSTIPATION	CONSTIPATION	39		64	No	Moderate	None	Not recovered
				DIARRHEA	DIARRHEA	8	1	64	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	37		64	No	Moderate	None	Not recovered
			Nervous	ANXIETY	JITTERYNESS	4	1	64	No	Mild	None	Recovered
				DIZZINESS	DIZZINESS	2	3	64	No	Mild	None	Recovered
						8		64	No	Mild	None	Not recovered
				SOMNOLENCE	AM GROGGINESS	29		64	No	Moderate	None	Not recovered
					LETHARGY	42		64	No	Moderate	Dose reduced	Not recovered
			Skin	DIAPHORETIC	SWEATING	2	3	64	No	Mild	None	Recovered
			Special Senses	EYE IRRITATION	ITCHY EYES	14	14	64	No	Mild	None	Recovered
	81004	43/Female	Body	HEADACHE	HEADACHE	13	1	78	No	Mild	None	Recovered
						22	1	78	No	Mild	None	Recovered
						28	2	78	No	Mild	None	Recovered
						38	1	78	No	Mild	None	Recovered
						40	1	78	No	Mild	None	Recovered
						49	1	78	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Helfing	81004	43/Female	Body	HEADACHE	HEADACHE	53	2	78	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	13	50	78	No	Moderate	None	Recovered
				DRY MOUTH	DRY MOUTH	3	60	78	No	Mild	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	6		78	No	Moderate	None	Not recovered
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	3	5	78	No	Mild	None	Recovered
	81051	37/Female	Body	ASTHENIA	DECREASED EXERTIONAL ENDURANCE	1		26	No	Moderate	None	Not recovered
				HEADACHE	HEADACHE	2	2	26	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	7		26	No	Mild	None	Not recovered
				NAUSEA	NAUSEA	21		26	No	Moderate	None	Not recovered
			Nervous	NERVOUSNESS	INCREASED IRRITABILITY	8		26	No	Moderate	None	Not recovered
			Skin	DIAPHORETIC	COLD SWEATS	2		26	No	Moderate	None	Not recovered
				ECZEMA	INCREASED ECZEMA	26		26	No	Moderate	Drug permanently withdrawn	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Helfing	81051	37/Female	Skin	HAIR LOSS	HAIR LOSS	26		26	No	Mild	Drug permanently withdrawn	Not recovered
			Special Senses	BLURRED VISION	BLURRED VISION	7		26	No	Mild	None	Not recovered
	81052	39/Female	Body	HEADACHE	HEADACHE	1	28	20	No	Moderate	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	1	28	20	No	Moderate	None	Recovered
			Skin	DIAPHORETIC	INCREASED SWEATING WITH PILOERECTION	0	29	20	No	Moderate	None	Recovered
	81075	37/Female	Body	HEADACHE	HEADACHE	14	13	167	No	Moderate	None	Recovered
						50	1	167	No	Mild	None	Recovered
			Cardiovascular	TACHYCARDIA	INCREASED HEART RATE	0	2	167	No	Mild	None	Recovered
				VASODILATION	FLUSHING	34	72	167	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	5	1	167	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	11	57	167	No	Moderate	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	0	2	167	No	Mild	None	Recovered
						14	57	167	No	Moderate	None	Recovered
				SOMNILOQUISM	SLEEP TALKING	2	165	167	No	Mild	None	Recovered
			Skin	DIAPHORETIC	SWEATING	0	2	167	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Helfing	81076	23/Female	Body	HEADACHE	HEADACHE	32	11	171	No	Moderate	None	Recovered
					HEADACHES	17	5	171	No	Mild	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	12	67	171	No	Moderate	None	Recovered
			Skin	DIAPHORETIC	INCREASED PERSPIRATION	0	35	171	No	Moderate	None	Recovered
	81103	48/Female	Body	HEADACHE	HEADACHE	8	1	71	No	Mild	None	Recovered
						10	1	71	No	Mild	None	Recovered
						13	1	71	No	Mild	None	Recovered
				LOCALIZED PAIN	BACK OF LEGS ACHE	14		71	No	Moderate	None	Recovered
			Cardiovascular	VASODILATION	HOT FLASHES	0		71	No	Mild	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	6		71	No	Moderate	None	Not recovered
				NAUSEA	NAUSEA	0	16	71	No	Moderate	None	Recovered
			Nervous	AGITATION	AGITATION	4	12	71	No	Mild	None	Recovered
						28	2	71	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	0		71	No	Moderate	None	Not recovered
Hoopes	271021	29/Male	Body	HEADACHE	HEADACHES	8	7	57	No	Moderate	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Hoopes	271021	29/Male	Digestive	DRY MOUTH	XEROSTOMA	7	8	57	No	Moderate	None	Recovered
			Nervous	INSOMNIA	MIDDLE INSOMNIA	7	8	57	No	Moderate	None	Recovered
			Urogenital	EJACULATION ABNORMAL	PAINFUL EJACULATION	4	44	57	No	Mild	None	Recovered
	271022	42/Female	Body	HEADACHE	HEADACHES	5	25	77	No	Moderate	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	1		77	No	Mild	None	Not recovered
				NAUSEA	NAUSEA	5	25	77	No	Moderate	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	5	25	77	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	7	23	77	No	Moderate	None	Recovered
	271045	18/Male	Digestive	APPETITE DECREASED	DECREASED APPETITE	2		38	No	Mild	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	2	7	38	No	Mild	None	Recovered
						28		38	No	Moderate	None	Not recovered
Liebowitz	91005	54/Female	Digestive	DRY MOUTH	DRY MOUTH	3	25	36	No	Mild	None	Recovered
			Nervous	ANXIETY	JITTERNESS	25	3	36	No	Mild	None	Recovered
				DIZZINESS	DIZZINESS	3	1	36	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Liebowitz	91005	54/Female	Nervous	DIZZINESS	LIGHTHEADEDNESS	4	1	36	No	Mild	None	Recovered
	91006	44/Female	Body	HEADACHE	WORSENING OF HEADACHE	8	7	56	No	Moderate	None	Recovered
				LOCALIZED PAIN	BILATERAL LEG PAIN	47		56	No	Mild	None	Not recovered
			Cardiovascular	VASODILATION	HEAT FEELINGS (FLUSHING)	45		56	No	Mild	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	2	45	56	No	Mild	None	Recovered
						48		56	No	Mild	None	Not recovered
				DRY MOUTH	DRY MOUTH	15	32	56	No	Mild	None	Recovered
						48		56	No	Mild	None	Not recovered
			Nervous	DIZZINESS	DIZZINESS	49	2	56	No	Mild	None	Recovered
			Special Senses	BLURRED VISION	BLURRY VISION	28	19	56	No	Mild	None	Recovered
	91036	38/Male	Nervous	ANXIETY	INCREASED ANXIETY	2		4	No	Severe	Drug permanently withdrawn	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Liebowitz	91036	38/Male	Nervous	DEPRESSIVE SYMPTOMS	INCREASED DEPRESSION	2		4	No	Severe	Drug permanently withdrawn	Not recovered
				HOSTILITY	ANGRY MOOD	2		4	No	Severe	Drug permanently withdrawn	Not recovered
				INSOMNIA	SLEEPING DIFFICULTIES	2		4	No	Severe	Drug permanently withdrawn	Not recovered
	91097	38/Female	Digestive	APPETITE INCREASED	INCREASED APPETITE	23		54	No	Moderate	None	Not recovered
				DRY MOUTH	DRY MOUTH	1	7	54	No	Mild	None	Recovered
						13	2	54	No	Mild	None	Recovered
						27		54	No	Mild	None	Not recovered
				DYSPEPSIA	HEARTBURN	0	20	54	No	Moderate	None	Recovered
	91098	23/Female	Cardiovascular	HYPOTENSION POSTURAL	ORTHOSTATIC HYPOTENSION	5	4	7	No	Severe	Drug permanently withdrawn	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Liebowitz	91137	40/Male	Body	HEADACHE	HEADACHE	35		57	No	Mild	None	Not recovered
			Digestive	DRY MOUTH	DRY MOUTH	35		57	No	Mild	None	Not recovered
			Nervous	DIZZINESS	DIZZINESS	29		57	No	Mild	None	Not recovered
			Respiratory	RHINITIS	RUNNY NOSE	43		57	No	Mild	None	Not recovered
			Special Senses	DRY EYES	DRY EYES	31		57	No	Mild	None	Not recovered
	91138	45/Female	Body	HEADACHE	HEADACHES	30		50	No	Mild	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	2	14	50	No	Mild	None	Recovered
			Nervous	INSOMNIA	INITIAL INSOMNIA	16		50	No	Mild	None	Not recovered
Londborg	101009	36/Female	Body	HEADACHE	HEADACHE	1	8	21	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	20		21	No	Mild	None	Not recovered
			Nervous	CONCENTRATION IMPAIRED	DECREASED CONCENTRATION	15		21	No	Moderate	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Londborg	101009	36/Female	Nervous	SOMNOLENCE	SOMNOLENCE	1		21	No	Moderate	None	Not recovered
	101010	51/Female	Body	HEADACHE	HEADACHE	9	1	57	No	Mild	None	Recovered
			Cardiovascular	HYPERTENSION	ELEVATED BLOOD PRESSURE	56	8	57	No	Mild	None	Recovered
				TACHYCARDIA	TACHYCARDIA	34	10	57	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	1		57	No	Mild	None	Not recovered
			Nervous	DIZZINESS	DIZZINESS	5		57	No	Mild	None	Not recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	1		57	No	Mild	None	Not recovered
	101043	31/Female	Nervous	DIZZINESS	DIZZINESS	44	14	65	No	Mild	None	Recovered
				INSOMNIA	EARLY MORNING AWAKENING (INSOMNIA-LATE)	2	29	65	No	Mild	None	Recovered
	101044	41/Female	Nervous	CNS STIMULATION	CNS STIMULATION	1	10	211	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Londborg	101044	41/Female	Nervous	INSOMNIA	INSOMNIA	7		211	No	Moderate	None	Not recovered
			Skin	DIAPHORETIC	SWEATING	1	50	211	No	Moderate	None	Recovered
Lydiard	221033	44/Male	Nervous	ANXIETY	JITTERINESS	1	5	141	No	Mild	None	Recovered
	221034	40/Female	Body	HEADACHE	HEADACHE	15	2	42	No	Mild	None	Recovered
						21	2	42	No	Moderate	None	Recovered
						24	1	42	No	Moderate	None	Recovered
						28	2	42	No	Moderate	None	Recovered
						36	1	42	No	Moderate	None	Recovered
						40	1	42	No	Moderate	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	38	1	42	No	Mild	None	Recovered
			Skin	DIAPHORETIC	NIGHT SWEATS	0	32	42	No	Moderate	None	Recovered
	221129	51/Male	Cardiovascular	VASODILATION	HOT FLASHES	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Nervous	AGITATION	AGITATION	1		6	No	Mild	Drug permanently withdrawn	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Lydiard	221129	51/Male	Nervous	INSOMNIA	INSOMNIA	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Skin	DIAPHORETIC	EXCESSIVE PERSPIRATION	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
			Urogenital	IMPOTENCE	IMPOTENCE	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
				URINATION IMPAIRED	URINARY HESITANCY	1		6	No	Moderate	Drug permanently withdrawn	Not recovered
	221130	51/Female	Cardiovascular	VASODILATION	HOT FLASHES	2			No	Moderate	None	Unknown
			Nervous	INSOMNIA	INSOMNIA	8	18		No	Mild	None	Recovered
McGrath	111057	48/Male	Body	HEADACHE	HEADACHE	0		18	No	Moderate	Dose reduced	Not recovered
			Urogenital	URINATION IMPAIRED	DIFFCULTY URINATING	0		18	No	Moderate	Drug permanently withdrawn	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
McGrath	111058	20/Female	Digestive	APPETITE DECREASED	DECREASED APPETITE	1	1	58	No	Mild	None	Recovered
				APPETITE INCREASED	INCREASED APPETITE	24	2	58	No	Mild	None	Recovered
						27	1	58	No	Mild	None	Recovered
						29	1	58	No	Mild	None	Recovered
						31	4	58	No	Mild	None	Recovered
						36	7	58	No	Severe	None	Recovered
						43	15	58	No	Moderate	None	Recovered
				CONSTIPATION	CONSTIPATION	17	1	58	No	Mild	Drug temporarily withdrawn	Recovered
				DYSPEPSIA	UPSET BOWELS	2	1	58	No	Mild	None	Recovered
				NAUSEA	NAUSEA	3	1	58	No	Mild	None	Recovered
						5	1	58	No	Mild	None	Recovered
			Nervous	SOMNOLENCE	SLEEPY	43	1	58	No	Mild	None	Recovered
						45	1	58	No	Mild	None	Recovered
						47	3	58	No	Mild	None	Recovered
					TOO SLEEPY	4	1	58	No	Mild	None	Recovered
						6	1	58	No	Mild	None	Recovered
	111171	50/Male	Digestive	CONSTIPATION	MILD CONSTIPATION	2	22	57	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
McGrath	111171	50/Male	Digestive	DRY MOUTH	DRY MOUTH	1	65	57	No	Moderate	None	Recovered
			Nervous	SOMNOLENCE	DROWSINESS	0	66	57	No	Moderate	None	Recovered
			Urogenital	EJACULATION ABNORMAL	EJACULATORY DISCOMFORT	12	12	57	No	Mild	None	Recovered
				URINATION IMPAIRED	TROUBLE URINATING	1	65	57	No	Severe	None	Recovered
Moreines	121007	33/Female	Body	ASTHENIA	WEAKNESS	48	45	93	No	Moderate	None	Recovered
				CHILLS	CHILLS	1	4	93	No	Mild	None	Recovered
				FATIGUE	INCREASED FATIGUE	1	19	93	No	Severe	None	Recovered
			Digestive	APPETITE DECREASED	DECREASED APPETITE	1	20	93	No	Moderate	None	Recovered
				DRY MOUTH	DRY MOUTH	3	73	93	No	Moderate	None	Recovered
				INCREASED THIRST	INCREASED THIRST	3	73	93	No	Moderate	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	38	55	93	No	Moderate	None	Recovered
				NERVOUSNESS	IRRITABILITY	1	20	93	No	Moderate	None	Recovered
				SOMNOLENCE	DROWSINESS	1	21	93	No	Severe	None	Recovered
			Skin	DIAPHORETIC	SWEATING	29	41	93	No	Moderate	None	Recovered
				RASH	RASH ON LEFT ARM	38	5	93	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Munjack	131011	56/Male	Digestive	DRY MOUTH	DRY MOUTH	53	10	198	No	Moderate	None	Recovered
	131125	34/Female	Body	HEADACHE	HEADACHE	19	2	74	No	Severe	None	Recovered
						57	1	74	No	Severe	None	Recovered
			Cardiovascular	VASODILATION	FLUSHING	19	9	74	No	Moderate	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	32		74	No	Mild	None	Not recovered
				DYSPEPSIA	HEARTBURN	21	2	74	No	Moderate	None	Recovered
				NAUSEA	NAUSEA	4	3	74	No	Severe	None	Recovered
						20	2	74	No	Mild	None	Recovered
				VOMITING	VOMITING	6	1	74	No	Moderate	None	Recovered
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	2	56	74	No	Moderate	None	Recovered
			Skin	DERMATITIS	DERMATITIS	31	34	74	No	Mild	None	Recovered
				DIAPHORETIC	NIGHT SWEATS	20	8	74	No	Moderate	None	Recovered
	131126	45/Male	Nervous	INSOMNIA	INCREASED INSOMNIA	0		57	No	Severe	None	Not recovered
	131143	39/Female	Body	REACTION UNEVALUABLE	SPACY FEELING (LASTING 2-4 HOURS AFTER DOSING)	1	5	56	No	Moderate	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Munjack	131143	39/Female	Digestive	APPETITE DECREASED	DECREASE APPETITE	1	5	56	No	Moderate	None	Recovered
				DRY MOUTH	DRY MOUTH	1	14	56	No	Moderate	None	Recovered
			Nervous	INSOMNIA	INSOMNIA-INCREASED	1	5	56	No	Moderate	None	Recovered
			Skin	DIAPHORETIC	INCREASE SWEATING (LASTING 2-4 HOURS AFTER DOSING)	1	5	56	No	Moderate	None	Recovered
			Special Senses	TASTE PERVERSION	METAL TASTE IN MOUTH	1	5	56	No	Moderate	None	Recovered
	131144	33/Female	Digestive	DRY MOUTH	DRY MOUTH	23	5	56	No	Mild	None	Recovered
Nelson	141041	55/Female	Body	HEADACHE	HEADACHES	0		57	No	Moderate	None	Not recovered
			Cardiovascular	PALPITATION	HEART BEATING FASTER ONE MOMENT	14	8	57	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	0	8	57	No	Moderate	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Nelson	141041	55/Female	Digestive	DRY MOUTH	DRY MOUTH	42		57	No	Mild	None	Not recovered
			Skin	DIAPHORETIC	SWEATING	7	8	57	No	Mild	None	Recovered
			Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	7	15	57	No	Mild	None	Recovered
				TINNITUS	RINGING IN EARS	7	15	57	No	Mild	None	Recovered
Oldroyd	321055	38/Male	Body	ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	17	1		No	Moderate	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	1	3		No	Mild	None	Recovered
						20	1		No	Mild	None	Recovered
				NAUSEA	NAUSEA	36	2		No	Mild	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	36	2		No	Mild	None	Recovered
			Urogenital	EJACULATION ABNORMAL	EJACULATORY DYSFUNCTION	4	2		No	Mild	None	Recovered
	321056	44/Male	Digestive	DIARRHEA	DIARRHEA	7	2	8	No	Severe	Drug permanently withdrawn	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Oldroyd	321056	44/Male	Urogenital	DISORDER TESTICLE	TESTICULAR REFRACTION	7	1	8	No	Moderate	Drug permanently withdrawn	Recovered
				EJACULATION ABNORMAL	SPONTANEOUS EJACULATION	7	1	8	No	Moderate	Drug permanently withdrawn	Recovered
	321087	55/Male	Urogenital	RETENTION URINARY	URINARY RETENSION	8	24	171	No	Moderate	None	Recovered
Prover	261023	33/Female	Body	HEADACHE	HEADACHE	25	1	56	No	Mild	None	Recovered
						27	1	56	No	Moderate	None	Recovered
						35	1	56	No	Moderate	None	Recovered
					INTERMITTENT HEADACHES	41		56	No	Moderate	None	Unknown
			Digestive	DRY MOUTH	DRY MOUTH	0		56	No	Mild	None	Unknown
Rapaport	151037	62/Female	Digestive	APPETITE DECREASED	DECREASED APPETITIE	8	9	240	No	Mild	None	Recovered
	151038	52/Male	Body	HEADACHE	HEADACHES	0	43	141	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Rapaport	151038	52/Male	Digestive	CONSTIPATION	CONSTIPATION	7	15	141	No	Mild	None	Recovered
			Nervous	PARESTHESIA	HYPERSENSITIVITY - SCALP TINGLING	39	4	141	No	Mild	None	Recovered
	151085	50/Female	Body	HEADACHE	HEADACHES	6	4	14	No	Mild	None	Recovered
			Cardiovascular	PALPITATION	RACING HEART	0	8	14	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	0		14	No	Mild	None	Not recovered
			Skin	DIAPHORETIC	SWEATING	0	4	14	No	Mild	None	Recovered
			Special Senses	BLURRED VISION	BLURRED VISION	0		14	No	Moderate	Drug permanently withdrawn	Not recovered
	151086	45/Female	Body	GENERALIZED EDEMA	EDEMA	29		38	No	Moderate	Drug permanently withdrawn	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	0		38	No	Mild	Drug permanently withdrawn	Not recovered
				DRY MOUTH	DRY MOUTH	4		38	No	Mild	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Rapaport	151086	45/Female	Skin	RASH	RASH (ON BREAST)	5	8	38	No	Mild	None	Recovered
	151095	49/Male	Body	GENERALIZED EDEMA	EDEMA	55	4	156	No	Mild	None	Recovered
				HEADACHE	HEADACHES	33		156	No	Mild	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	54	20	156	No	Mild	None	Recovered
			Special Senses	TINNITUS	TINITUS	1		156	No	Mild	None	Not recovered
			Urogenital	POLYURIA	POLYURIA (FREQUENT URINATION)	1	28	156	No	Mild	None	Recovered
				URINATION IMPAIRED	URINARY HESITANCY	14	15	156	No	Mild	None	Recovered
	151096	60/Male	Cardiovascular	HYPOTENSION POSTURAL	ORTHOSTATIC HYPOTENSION	17	1	93	No	Moderate	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	24	1	93	No	Mild	None	Recovered
						47	40	93	No	Mild	None	Recovered
			Urogenital	IMPOTENCE	ERECTILE DYSFUNCTION	13	44	93	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Rapaport	151096	60/Male	Urogenital	URINATION IMPAIRED	DELAYED URINATION	27	40	93	No	Mild	None	Recovered
	151099	52/Female	Body	ABDOMINAL DISTENSION	BLOATING	1		77	No	Mild	None	Not recovered
				CHILLS	CHILLS	44	1	77	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	1	70	77	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	1	40	77	No	Mild	None	Recovered
				NAUSEA	NAUSEA	0	9	77	No	Mild	None	Recovered
				VOMITING	VOMITING	44	1	77	No	Mild	None	Recovered
			Skin	DIAPHORETIC	SWEATING	44	1	77	No	Mild	None	Recovered
			Special Senses	TASTE PERVERSION	TASTE DISTURBANCE OF SENSATION	51	11	77	No	Mild	None	Recovered
	151100	42/Female	Body	HEADACHE	HEADACHES	7		36	No	Mild	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	34		36	No	Severe	Drug permanently withdrawn	Not recovered
	151117	49/Female	Digestive	DRY MOUTH	DRY MOUTH	0		56	No	Mild	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Rapaport	151117	49/Female	Nervous	INSOMNIA	INSOMNIA	0	3	56	No	Mild	None	Recovered
				RESTLESSNESS	RESTLESSNESS	0	5	56	No	Mild	None	Recovered
	151118	47/Male	Nervous	INSOMNIA	INSOMNIA	9	2	55	No	Mild	None	Recovered
	151153	44/Male	Body	HEADACHE	HEADACHES	6	6	20	No	Mild	None	Recovered
			Cardiovascular	PALPITATION	HEART PALPITATIONS	1	1	20	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	14		20	No	Mild	None	Not recovered
				NAUSEA	NAUSEA	2	2	20	No	Mild	None	Recovered
			Nervous	DIZZINESS	DIZZINESS	1	1	20	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	1	14	20	No	Mild	None	Recovered
				SOMNOLENCE	LETHARGY	2	13	20	No	Mild	None	Recovered
				TREMOR	TREMBLING	1	3	20	No	Mild	None	Recovered
			Urogenital	EJACULATION ABNORMAL	DELAYED EJACULATION	3		20	No	Mild	Drug permanently withdrawn	Not recovered
				IMPOTENCE	ERECTILE DYSFUNCTION	0	17	20	No	Mild	None	Recovered
				PAIN TESTICULAR	TESTICLE PAIN	3	19	20	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Rapaport	151153	44/Male	Urogenital	URINATION IMPAIRED	URINARY HESITANCY	1	14	20	No	Mild	None	Recovered
Smith	281025	41/Female	Digestive	CONSTIPATION	CONSTIPATION	3		3	No	Moderate	Drug permanently withdrawn	Not recovered
			Nervous	ANXIETY	ANXIETY	3		3	No	Moderate	Drug permanently withdrawn	Not recovered
				DIZZINESS	DIZZY	3		3	No	Moderate	Drug permanently withdrawn	Not recovered
				INSOMNIA	INSOMNIA	0		3	No	Moderate	Drug permanently withdrawn	Not recovered
	281026	46/Female	Digestive	DRY MOUTH	DRY MOUTH	0		49	No	Moderate	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	5		49	No	Moderate	None	Not recovered
				NERVOUSNESS	IRRITABLE	5		49	No	Moderate	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Smith	281101	40/Female	Body	CHILLS	COLD FLASH	1	3	56	No	Mild	None	Recovered
			Cardiovascular	VASODILATION	HOT FLUSHES	1	3	56	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	1		56	No	Mild	None	Not recovered
			Nervous	INSOMNIA	INSOMNIA	19		56	No	Moderate	None	Not recovered
	281102	44/Female	Body	CHILLS	COLD FLASH	0	29	68	No	Mild	None	Recovered
				HEADACHE	HEADACHE	4	25	68	No	Mild	None	Recovered
			Cardiovascular	VASODILATION	HOT FLASH	0	29	68	No	Mild	None	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	6		68	No	Mild	None	Not recovered
				DRY MOUTH	DRY MOUTH	1	58	68	No	Mild	None	Recovered
			Nervous	DIZZINESS	DIZZY	17	32	68	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	37	24	68	No	Mild	None	Recovered
				PARESTHESIA	PARAESTHESIA	1	2	68	No	Mild	None	Recovered
	281107	61/Female	Body	HEADACHE	HEADACHE	0		32	No	Moderate	None	Not recovered
			Digestive	CONSTIPATION	CONSTIPATION	28		32	No	Mild	None	Not recovered
				DRY MOUTH	DRY MOUTH	0		32	No	Moderate	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Smith	281107	61/Female	Nervous	INSOMNIA	INSOMNIA	0		32	No	Severe	None	Not recovered
			Skin	DIAPHORETIC	SWEATING	2		32	No	Mild	None	Not recovered
	281108	53/Female	Body	CHILLS	COLD FLASH	2	5	91	No	Mild	None	Recovered
			Cardiovascular	VASODILATION	FACIAL FLUSHING	49	22	91	No	Mild	None	Recovered
					HOT FLASH	0	7	91	No	Mild	None	Recovered
						8	23	91	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	0	71	91	No	Mild	None	Recovered
				DYSPEPSIA	UPSET STOMACH	0	6	91	No	Mild	None	Recovered
			Musculo-Skeletal	MYALGIA	MUSCLE ACHES	37	10	91	No	Mild	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	40	43	91	No	Mild	None	Recovered
				SOMNOLENCE	DROWSY	0	7	91	No	Mild	None	Recovered
			Skin	DIAPHORETIC	SWEATING	7	40	91	No	Mild	None	Recovered
Telew	171015	45/Female	Digestive	DRY MOUTH	DRY MOUTH	4		85	No	Mild	None	Not recovered
			Special Senses	EYE PAIN	BURNING EYES	8		85	No	Mild	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Telew	171016	37/Male	Digestive	CONSTIPATION	CONSTIPATION	3			No	Moderate	None	Unknown
				DRY MOUTH	DRY MOUTH	0	15		No	Moderate	None	Recovered
			Urogenital	RETENTION URINARY	URINARY RETENTION	2	35		No	Severe	None	Recovered
	171027	52/Female	Body	HEADACHE	HEADACHE	26	2	35	No	Moderate	None	Recovered
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	10	2	35	No	Mild	None	Recovered
	171028	45/Female	Nervous	INSOMNIA	INSOMNIA	10	3	24	No	Mild	None	Recovered
	171061	47/Female	Digestive	APPETITE DECREASED	DECREASED APPETITE	15	3	35	No	Mild	None	Recovered
			Nervous	NERVOUSNESS	FEELING EDGY	18	3	35	No	Mild	None	Recovered
Thase	181083	58/Male	Nervous	INSOMNIA	SLEEP DIFFICULTY	1		143	No	Mild	None	Not recovered
				PARESTHESIA	TINGLING IN UPPER SPINE	1	37	143	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Thase	181083	58/Male	Special Senses	TINNITUS	TINNITUS CHANGED TONE-"HIGH FREQUENCY TO LOW RUMBLE"	14		143	No	Mild	None	Not recovered
			Urogenital	DYSURIA	SLIGHT URINARY ITCHING SENSATION	1		143	No	Mild	None	Not recovered
				NOCTURIA	URINARY FREQUENCY AT NIGHT	1		143	No	Mild	None	Not recovered
				URINATION IMPAIRED	URINARY HESITANCY	1	37	143	No	Mild	None	Recovered
	181084	32/Male	Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD FEET	3	62	120	No	Moderate	Dose reduced	Recovered
					COLD HANDS	3	62	120	No	Moderate	Dose reduced	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	24	27	120	No	Mild	Dose increased	Recovered

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Thase	181084	32/Male	Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	21	15	120	No	Mild	Dose increased	Recovered with sequelae
			Nervous	INSOMNIA	INSOMNIA	32	20	120	No	Moderate	Dose reduced	Recovered
			Skin	DIAPHORETIC	INCREASE SWEAT WITH EXERTION	10	14	120	No	Mild	None	Recovered
					SWEATING	1	9	120	No	Moderate	None	Recovered
			Urogenital	URINATION IMPAIRED	SLOWED URINARY STREAM	1	46	120	No	Mild	None	Recovered
	181105	37/Female	Nervous	DEPRESSIVE SYMPTOMS	INCREASED SEVERITY DEPRESSED MOOD	26	4	56	No	Moderate	None	Recovered
				INSOMNIA	INSOMNIA	3	6	56	No	Moderate	None	Recovered
				NERVOUSNESS	INCREASE IRRITABILITY	23	7	56	No	Moderate	None	Recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	2	19	56	No	Moderate	None	Recovered
			Urogenital	DISORDER MENSTRUAL NEC	MENSTRUAL CHANGES	9		56	No	Mild	None	Not recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Thase	181106	28/Male	Skin	DIAPHORETIC	COLD SWEATS	0		15	No	Severe	None	Not recovered
			Special Senses	TASTE PERVERSION	METALLIC TASTE	0		15	No	Mild	Drug permanently withdrawn	Not recovered
			Urogenital	DYSURIA	URINARY PRESSURE	2		15	No	Moderate	None	Not recovered
				EJACULATION ABNORMAL	SPONTANEOUS EJACULATORY DISCHARGE	3	1	15	No	Mild	None	Recovered
						9		15	No	Mild	Drug permanently withdrawn	Not recovered
	181135	31/Female	Digestive	DRY MOUTH	DRY MOUTH	2	25	37	No	Mild	None	Recovered
				DYSPEPSIA	HEARTBURN	10	32	37	No	Moderate	None	Recovered
			Nervous	AGITATION	EPISODIC AGITATION	4	5	37	No	Moderate	None	Recovered
				DIZZINESS	LIGHTHEADED	12	1	37	No	Mild	None	Recovered
				NERVOUSNESS	IRRITABILITY	18	33	37	No	Severe	None	Recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	3	3	37	No	Mild	None	Recovered

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Thase	181135	31/Female	Skin	DIAPHORETIC	INCREASED SWEATING EXERCISE	15	24	37	No	Moderate	None	Recovered
				DISORDER SKIN NEC	SKIN ABNORMALITIES	10	41	37	No	Moderate	None	Recovered
			Special Senses	BLURRED VISION	BLURRED VISION	10	1	37	No	Mild	None	Recovered
	181136	55/Female	Body	HEADACHE	HEADACHE	14	1	57	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	26		57	No	Moderate	Dose increased	Not recovered
			Nervous	INSOMNIA	RESTLESS SLEEP	1	3	57	No	Mild	None	Recovered
						8		57	No	Moderate	None	Not recovered
Trivedi	191013	36/Female	Body	HEADACHE	HEADACHE (POST-OCCIPITAL)	41	3	44	No	Mild	None	Recovered
				NECK PAIN	NECK ACHE	8	2	44	No	Mild	None	Recovered
			Digestive	NAUSEA	NAUSEA	1	7	44	No	Mild	None	Recovered
						13	1	44	No	Mild	None	Recovered
						34	8	44	No	Mild	None	Recovered

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Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Trivedi	191013	36/Female	Nervous	DIZZINESS	DIZZINESS	2	11	44	No	Mild	None	Recovered
						16	5	44	No	Mild	None	Recovered
						36	2	44	No	Mild	None	Recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	36	2	44	No	Mild	None	Recovered
						40		44	No	Mild	None	Not recovered
			Special Senses	TINNITUS	TINNITUS (R) EAR	40	1	44	No	Mild	None	Recovered
	191014	47/Male	Body	CHILLS	COLD FLASHES	0	17	156	No	Mild	None	Recovered
				HEADACHE	HEADACHE	34	1	156	No	Mild	None	Recovered
			Cardiovascular	VASODILATION	HOT FLASHES	0	17	156	No	Mild	None	Recovered
			Digestive	APPETITE DECREASED	DECREASED APPETITE	2	43	156	No	Mild	None	Recovered
				CONSTIPATION	CONSTIPATION	5	2	156	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	0	33	156	No	Mild	None	Recovered
				NAUSEA	NAUSEA	9	3	156	No	Moderate	None	Recovered
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	22		156	No	Mild	None	Not recovered
				INSOMNIA	INSOMNIA	0	16	156	No	Moderate	None	Recovered

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Trivedi	191014	47/Male	Nervous	PARESTHESIA	INTERMITTENT TINGLING OF ARMS	0	8	156	No	Mild	None	Recovered
			Skin	DIAPHORETIC	INCREASED SWEATING	0	47	156	No	Moderate	None	Recovered
			Urogenital	URINATION IMPAIRED	DECREASED FORCE OF URINARY STREAM	1	30	156	No	Moderate	None	Recovered
Walsh	171016	37/Male	Metabolic and Nutritional	BILIRUBINEMIA	ABNORMAL BILIRUBIN - INCREASE	29			No	Mild	None	Unknown
	171027	52/Female	Body	HEADACHE	HEADACHE	20	6	35	No	Mild	None	Recovered
			Nervous	INSOMNIA	INSOMNIA	28		35	No	Moderate	None	Not recovered
				MANIC SYMPTOMS	RACING THOUGHTS	12		35	No	Moderate	None	Not recovered
			Skin	DISORDER HAIR	PILOERECTION	1	6	35	No	Moderate	None	Recovered
	171028	45/Female	Digestive	DRY MOUTH	DRY MOUTH	1	4	24	No	Mild	None	Recovered

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Walsh	171028	45/Female	Digestive	DRY MOUTH	DRY MOUTH	1	4	24	No	Mild	None	Recovered
				DYSPEPSIA	HEART BURN	18	4	24	No	Mild	None	Recovered
				NAUSEA	NAUSEA	17	3	24	No	Mild	None	Recovered
			Nervous	ANXIETY	JITTERY	1	12	24	No	Moderate	None	Recovered
				CONCENTRATION IMPAIRED	IMPAIRED CONCENTRATION	1	4	24	No	Moderate	None	Recovered
				DIZZINESS	DIZZINESS	17	2	24	No	Mild	None	Recovered
					LIGHT HEADED	17		24	No	Mild	None	Not recovered
				INSOMNIA	INSOMNIA	1	12	24	No	Mild	None	Recovered
	171061	47/Female	Digestive	DRY MOUTH	DRY MOUTH	1		35	No	Mild	None	Not recovered
				NAUSEA	NAUSEA	26		35	No	Mild	None	Not recovered
			Metabolic and Nutritional	PERIPHERAL EDEMA	FEET SWELLING	27		35	No	Mild	None	Not recovered
			Nervous	MANIC SYMPTOMS	HYPOMANIA	27		35	No	Mild	Drug permanently withdrawn	Not recovered
	171062	52/Female	Body	HEADACHE	HEADACHE	9	2	64	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Walsh	171062	52/Female	Body	HEADACHE	HEADACHES	9	2	64	No	Mild	None	Recovered
			Cardiovascular	TACHYCARDIA	TACHYCARDIA	0	2	64	No	Mild	None	Recovered
				VASODILATION	HOT FLASHES	0		64	No	Mild	None	Not recovered
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	0	4	64	No	Mild	None	Recovered
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	2	49	64	No	Mild	None	Recovered
				NIGHTMARES	NIGHTMARES	11	20	64	No	Mild	None	Recovered
				SOMNOLENCE	SEDATION	0	5	64	No	Mild	None	Recovered
	171063	27/Male	Digestive	DRY MOUTH	DRY MOUTH	0	20	88	No	Mild	None	Recovered
			Nervous	ANXIETY	FEELING WIRED	0	39	88	No	Mild	None	Recovered
				INSOMNIA	INSOMNIA	0	12	88	No	Moderate	None	Recovered
						11	28	88	No	Mild	None	Recovered
			Skin	DIAPHORETIC	COLD SWEATS	1	11	88	No	Mild	None	Recovered
	171064	21/Female	Cardiovascular	VASODILATION	HOT FLASHES	4	8	8	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	1	10	8	No	Mild	None	Recovered
Zajecka	201067	31/Male	Body	CHEST PAIN	CHEST PAIN	5	2	120	No	Mild	None	Recovered
						11	2	120	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Zajecka	201067	31/Male	Body	CHILLS	COLD SENSATION WHILE EXERCISING	39	59	120	No	Mild	None	Recovered
					COLD SENSATIONS THROUGHOUT DAY	48	1	120	No	Moderate	None	Recovered
			Cardiovascular	VASODILATION	HEAT FLASHES	56	17	120	No	Moderate	None	Recovered
					HEAT SENSATIONS	55	2	120	No	Mild	None	Recovered
			Nervous	DIZZINESS	DIZZINESS WHEN STANDING UP	36	64	120	No	Mild	None	Recovered
					LIGHT HEADEDNESS WHEN STANDING UP	36	64	120	No	Mild	None	Recovered
				LIBIDO DECREASED	DECREASE IN LIBIDO	3	83	120	No	Mild	None	Recovered
				PARESTHESIA	TINGLING IN ARMS	1	86	120	No	Moderate	None	Recovered
					TINGLING IN HEAD	1	86	120	No	Moderate	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Zajecka	201067	31/Male	Nervous	PARESTHESIA	TINGLING IN LEGS	1	86	120	No	Moderate	None	Recovered
				RESTLESSNESS	RESTLESSNESS	0	3	120	No	Mild	None	Recovered
			Respiratory	DYSPNEA	SHORTNESS OF BREATH	11	2	120	No	Mild	None	Recovered
			Urogenital	EJACULATION ABNORMAL	DELAYED EJACULATION	2	15	120	No	Mild	None	Recovered
				IMPOTENCE	UNABLE TO REACH FULL ERECTION	3	22	120	No	Mild	None	Recovered
				RETENTION URINARY	SENSATION OF URINARY RETENTION	1	15	120	No	Mild	None	Recovered
				URINATION IMPAIRED	DIMINISHED FLOW OF URINE	1	15	120	No	Mild	None	Recovered
	201068	37/Female	Body	ASTHENIA	TIREDNESS	1	3	94	No	Mild	None	Recovered
				HEADACHE	HEADACHE	6	12	94	No	Mild	None	Recovered
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	1	65	94	No	Mild	None	Recovered
				CONSTIPATION	CONSTIPATION	2	77	94	No	Mild	None	Recovered
				DRY MOUTH	DRY MOUTH	3	61	94	No	Mild	None	Recovered
				HEMORRHOID	HEMORROIDS	15	64	94	No	Mild	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Zajecka	201068	37/Female	Nervous	DIZZINESS	LIGHT HEADEDNESS	3	3	94	No	Mild	None	Recovered
				PARESTHESIA	HEAD TINGLING	1	17	94	No	Mild	None	Recovered
						24	40	94	No	Mild	None	Recovered
				SOMNOLENCE	SLEEPINESS	1	3	94	No	Mild	None	Recovered
			Respiratory	RHINITIS	DRY NASAL PASSAGES	3	61	94	No	Mild	None	Recovered
			Skin	DIAPHORETIC	SWEATING	24	19	94	No	Mild	None	Recovered
			Urogenital	OLIGURIA	DECREASED FREQUENCY OF URINATION	21	43	94	No	Mild	None	Recovered
	201091	34/Female	Body	ASTHENIA	TIREDNESS	3		8	No	Mild	None	Not recovered
				HEADACHE	HEADACHE	3	4	8	No	Mild	None	Recovered
			Digestive	DRY MOUTH	DRY MOUTH	0		8	No	Mild	None	Not recovered
			Nervous	PARESTHESIA	HEAD TINGLING	0	7	8	No	Mild	None	Recovered
	201092	41/Female	Body	ASTHENIA	TIREDNESS	3	34	24	No	Mild	None	Recovered
				HEADACHE	INTERMITTENT HEADACHE	1	38	24	No	Severe	None	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events Related to Study Medication - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Intensity	Action Taken	Outcome
Zajecka	201092	41/Female	Digestive	CONSTIPATION	CONSTIPATION	2		24	No	Mild	None	Not recovered
	201123	43/Female	Digestive	CONSTIPATION	CONSTIPATION	14		56	No	Mild	None	Not recovered
				DRY MOUTH	DRY MOUTH	9		56	No	Mild	None	Not recovered
			Nervous	DIZZINESS	DIZZINESS	3	1	56	No	Mild	None	Recovered
						11		56	No	Mild	None	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events that Resulted in Early Termination - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Stdy Med.	Serious	Max. Intensity	Stdy Drug Rel.	Outcome
Dunner	211147	37/Female	Body	SUICIDE ATTEMPT	SUICIDE ATTEMPT	7	8	8	Yes	Severe	Yes	Recovered
Ferguson	241031	61/Male	Body	ABDOMINAL CRAMP	STOMACH CRAMPS	1	3	3	No	Moderate	Yes	Recovered
				REACTION UNEVALUABLE	HEAVY STOMACH	0	4	3	No	Mild	Yes	Recovered
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	1	3	3	No	Mild	Yes	Recovered
				CONSTIPATION	CONSTIPATION	1	3	3	No	Mild	Yes	Recovered
				NAUSEA	NAUSEA	0	4	3	No	Mild	Yes	Recovered
			Nervous	CONFUSION	CONFUSION	0	4	3	No	Mild	Yes	Recovered
				INSOMNIA	INSOMNIA	0	4	3	No	Mild	Yes	Recovered
Gilmer	61081	45/Female	Body	CHILLS	CHILLS	0	7	5	No	Mild	Yes	Recovered
			Cardiovascular	VASODILATION	FEELING FLUSHED	0	7	5	No	Mild	Yes	Recovered
			Digestive	CONSTIPATION	CONSTIPATION	0		5	No	Mild	Yes	Not recovered
			Nervous	ATAXIA	ATAXIA	7		5	No	Mild	Yes	Not recovered
				DIZZINESS	DIZZINESS	0		5	No	Severe	Yes	Not recovered
				SOMNOLENCE	DROWSINESS	0	7	5	No	Severe	Yes	Recovered
	61082	56/Female	Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPS	2		6	No	Moderate	Yes	Not recovered
				CHILLS	CHILLS	2		6	No	Moderate	Yes	Not recovered
			Digestive	NAUSEA	NAUSEA	1		6	No	Moderate	Yes	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events that Resulted in Early Termination - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Stdy Med.	Serious	Max. Intensity	Stdy Drug Rel.	Outcome
Gilmer	61082	56/Female	Nervous	INSOMNIA	INSOMNIA	0		6	No	Moderate	Yes	Not recovered
				MANIC SYMPTOMS	RACING THOUGHTS	3		6	No	Moderate	Yes	Not recovered
			Skin	DIAPHORETIC	SWEATING	0		6	No	Moderate	Yes	Not recovered
Halbreich	71077	56/Female	Nervous	INSOMNIA	INSOMNIA	2		64	No	Moderate	Yes	Not recovered
				NIGHTMARES	VIOLENT DREAMS	61		64	No	Moderate	Yes	Not recovered
Helfing	81051	37/Female	Skin	ECZEMA	INCREASED ECZEMA	26		26	No	Moderate	Yes	Not recovered
				HAIR LOSS	HAIR LOSS	26		26	No	Mild	Yes	Not recovered
Liebowitz	91036	38/Male	Nervous	ANXIETY	INCREASED ANXIETY	2		4	No	Severe	Yes	Not recovered
				DEPRESSIVE SYMPTOMS	INCREASED DEPRESSION	2		4	No	Severe	Yes	Not recovered
				HOSTILITY	ANGRY MOOD	2		4	No	Severe	Yes	Not recovered
				INSOMNIA	SLEEPING DIFFICULTIES	2		4	No	Severe	Yes	Not recovered
	91098	23/Female	Cardiovascular	HYPOTENSION POSTURAL	ORTHOSTATIC HYPOTENSION	5	4	7	No	Severe	Yes	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events that Resulted in Early Termination - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Stdy Med.	Serious	Max. Intensity	Stdy Drug Rel.	Outcome
Lydiard	221129	51/Male	Cardiovascular	VASODILATION	HOT FLASHES	1		6	No	Moderate	Yes	Not recovered
			Nervous	AGITATION	AGITATION	1		6	No	Mild	Yes	Not recovered
				INSOMNIA	INSOMNIA	1		6	No	Moderate	Yes	Not recovered
			Skin	DIAPHORETIC	EXCESSIVE PERSPIRATION	1		6	No	Moderate	Yes	Not recovered
			Urogenital	IMPOTENCE	IMPOTENCE	1		6	No	Moderate	Yes	Not recovered
				URINATION IMPAIRED	URINARY HESITANCY	1		6	No	Moderate	Yes	Not recovered
McGrath	111057	48/Male	Urogenital	URINATION IMPAIRED	DIFFCULTY URINATING	0		18	No	Moderate	Yes	Not recovered
Oldroyd	321056	44/Male	Digestive	DIARRHEA	DIARRHEA	7	2	8	No	Severe	Yes	Recovered
			Urogenital	DISORDER TESTICLE	TESTICULAR REFRACTION	7	1	8	No	Moderate	Yes	Recovered
				EJACULATION ABNORMAL	SPONTANEOUS EJACULATION	7	1	8	No	Moderate	Yes	Recovered
Rapaport	151085	50/Female	Special Senses	BLURRED VISION	BLURRED VISION	0		14	No	Moderate	Yes	Not recovered
	151086	45/Female	Body	GENERALIZED EDEMA	EDEMA	29		38	No	Moderate	Yes	Not recovered

Note: Onset day and stop day are relative to Baseline

Table AE10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events that Resulted in Early Termination - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Stdy Med.	Serious	Max. Intensity	Stdy Drug Rel.	Outcome
Rapaport	151086	45/Female	Digestive	CONSTIPATION	CONSTIPATION	0		38	No	Mild	Yes	Not recovered
	151100	42/Female	Nervous	INSOMNIA	INSOMNIA	34		36	No	Severe	Yes	Not recovered
	151153	44/Male	Urogenital	EJACULATION ABNORMAL	DELAYED EJACULATION	3		20	No	Mild	Yes	Not recovered
Smith	281025	41/Female	Digestive	CONSTIPATION	CONSTIPATION	3		3	No	Moderate	Yes	Not recovered
			Nervous	ANXIETY	ANXIETY	3		3	No	Moderate	Yes	Not recovered
				DIZZINESS	DIZZY	3		3	No	Moderate	Yes	Not recovered
				INSOMNIA	INSOMNIA	0		3	No	Moderate	Yes	Not recovered
	281107	61/Female	Nervous	INSOMNIA	INSOMNIA	0		32	No	Severe	Yes	Not recovered
Thase	181106	28/Male	Special Senses	TASTE PERVERSION	METALLIC TASTE	0		15	No	Mild	Yes	Not recovered
			Urogenital	EJACULATION ABNORMAL	SPONTANEOUS EJACULATORY DISCHARGE	9		15	No	Mild	Yes	Not recovered
	181135	31/Female	Nervous	NERVOUSNESS	IRRITABILITY	18	33	37	No	Severe	Yes	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Treatment Emergent Adverse Events that Resulted in Early Termination - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Stdy Med.	Serious	Max. Intensity	Stdy Drug Rel.	Outcome
Walsh	171061	47/Female	Nervous	MANIC SYMPTOMS	HYPOMANIA	27		35	No	Mild	Yes	Not recovered
Zajecka	201092	41/Female	Nervous	SUICIDAL TENDENCY	SUICIDAL DEPRESSION	22	12	24	Yes	Severe	No	Recovered

Note: Onset day and stop day are relative to Baseline

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
No of AE reported		.	.	651	.	.	325	.	.	54
Patients with at least one AE		69	53.9	.	38	29.7	.	18	14.1	.
Body	ABDOMINAL CRAMP	4	3.1	4	4	3.1	4	.	.	.
	ABDOMINAL DISTENSION	5	3.9	5	2	1.6	2	.	.	.
	ABDOMINAL PAIN GENERALIZED	1	0.8	1	1	0.8	1	.	.	.
	ABDOMINAL PAIN LOCALIZED	1	0.8	1	1	0.8	1	.	.	.
	ALLERGIC REACTION	2	1.6	2	2	1.6	2	.	.	.
	ASTHENIA	3	2.3	3	3	2.3	3	.	.	.
	BACK PAIN	11	8.6	13	5	3.9	5	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Body	CHEST PAIN	4	3.1	6	1	0.8	1	.	.	.
	CHILLS	15	11.7	18	4	3.1	4	.	.	.
	ENVIRONMENTAL ALLERGY	1	0.8	1	2	1.6	3	.	.	.
	FATIGUE	4	3.1	14	2	1.6	2	1	0.8	1
	FEVER	1	0.8	1	1	0.8	1	.	.	.
	FLU SYNDROME	4	3.1	4	3	2.3	3	.	.	.
	GENERALIZED EDEMA	3	2.3	3	1	0.8	1	.	.	.
	GENERALIZED PAIN	1	0.8	2	.	.	.	.	.	.
	HANGOVER	.	.	.	1	0.8	1	.	.	.
	HEADACHE	36	28.1	57	28	21.9	42	6	4.7	8

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Body	INFECTION FUNGAL NOS	1	0.8	1	.	.	.	.	.	.
	LOCALIZED EDEMA	.	.	.	1	0.8	1	.	.	.
	LOCALIZED PAIN	9	7.0	9	3	2.3	3	.	.	.
	NECK PAIN	3	2.3	5	.	.	.	.	.	.
	NECK RIGID	1	0.8	1	.	.	.	.	.	.
	NON-GENERALIZED WEAKNESS NOS	2	1.6	4	.	.	.	.	.	.
	REACTION UNEVALUABLE	7	5.5	11	2	1.6	2	.	.	.
	SUICIDE ATTEMPT	.	.	.	.	.	.	1	0.8	1
	TRAUMA	5	3.9	5	7	5.5	7	2	1.6	2

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Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Body	UPPER RESPIRATORY INFECTION	10	7.8	11	7	5.5	7	1	0.8	1
Cardiovascular	DISORDER PERIPHERAL VASCULAR	.	.	.	3	2.3	4	.	.	.
	HYPERTENSION	2	1.6	2	.	.	.	.	.	.
	HYPOTENSION	.	.	.	1	0.8	1	.	.	.
	HYPOTENSION POSTURAL	1	0.8	1	2	1.6	2	1	0.8	1
	MIGRAINE	1	0.8	1	1	0.8	1	1	0.8	1
	PALPITATION	6	4.7	6	2	1.6	2	.	.	.
	SINUS TACHYCARDIA	.	.	.	1	0.8	1	.	.	.
	TACHYCARDIA	5	3.9	5	.	.	.	.	.	.

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Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Cardiovascular	VASODILATION	17	13.3	22	4	3.1	4	.	.	.
Digestive	APPETITE DECREASED	11	8.6	11	4	3.1	4	.	.	.
	APPETITE INCREASED	2	1.6	5	2	1.6	2	1	0.8	1
	CONSTIPATION	22	17.2	26	14	10.9	14	.	.	.
	DIARRHEA	6	4.7	6	1	0.8	1	1	0.8	1
	DISORDER RECTAL	.	.	.	1	0.8	1	.	.	.
	DISORDER TONGUE	1	0.8	2	.	.	.	.	.	.
	DRY MOUTH	40	31.3	48	16	12.5	16	1	0.8	1
	DYSPEPSIA	11	8.6	11	9	7.0	11	2	1.6	2
	FLATULENCE	4	3.1	4	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Digestive	GASTRITIS	1	0.8	1	.	.	.	.	.	.
	GASTROENTERITIS	1	0.8	1	2	1.6	2	.	.	.
	GASTROINTESTINAL BLEEDING	.	.	.	1	0.8	1	.	.	.
	GINGIVITIS	.	.	.	1	0.8	1	.	.	.
	HEMORRHOID	2	1.6	2	.	.	.	.	.	.
	INCREASED THIRST	.	.	.	2	1.6	2	.	.	.
	LOOSE STOOLS NEC	2	1.6	2	.	.	.	.	.	.
	NAUSEA	18	14.1	26	8	6.3	8	2	1.6	2
	RECTAL BLEEDING	.	.	.	.	.	.	1	0.8	1

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Digestive	STOMATITIS APHTHOUS	1	0.8	1	.	.	.	.	.	.
	THROAT DRY	1	0.8	1	.	.	.	.	.	.
	TOOTH ABSCESS	.	.	.	1	0.8	1	.	.	.
	TOOTHACHE	1	0.8	1	1	0.8	1	.	.	.
	ULCER MOUTH	1	0.8	1	.	.	.	.	.	.
	VOMITING	3	2.3	3	1	0.8	1	.	.	.
Hemic and Lymphatic	ECCHYMOSIS/BRUISE	1	0.8	1	.	.	.	.	.	.
Metabolic and Nutritional	BILIRUBINEMIA	1	0.8	1	.	.	.	.	.	.
	HYPERCHOLESTEREMIA	1	0.8	1	.	.	.	.	.	.
	PERIPHERAL EDEMA	3	2.3	3	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Metabolic and Nutritional	WEIGHT DECREASE	1	0.8	1	.	.	.	.	.	.
	WEIGHT INCREASE	2	1.6	3	.	.	.	.	.	.
Musculo-Skeletal	CARPAL TUNNEL SYNDROME	.	.	.	1	0.8	1	.	.	.
	CRAMP LEGS	5	3.9	7	1	0.8	1	.	.	.
	JOINT STIFFNESS	1	0.8	1	.	.	.	.	.	.
	MUSCULAR WEAKNESS	.	.	.	1	0.8	2	.	.	.
	MYALGIA	5	3.9	5	1	0.8	1	.	.	.
Nervous	AGITATION	2	1.6	3	1	0.8	1	.	.	.
	AKATHISIA	1	0.8	1	.	.	.	.	.	.
	AMNESIA	1	0.8	2	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Nervous	ANXIETY	6	4.7	7	8	6.3	8	1	0.8	1
	ATAXIA	1	0.8	1	.	.	.	.	.	.
	CHANGE IN DREAMS	5	3.9	7	3	2.3	3	.	.	.
	CNS STIMULATION	1	0.8	1	.	.	.	.	.	.
	CONCENTRATION IMPAIRED	.	.	.	4	3.1	4	.	.	.
	CONFUSION	1	0.8	1	1	0.8	1	.	.	.
	DEPRESSIVE SYMPTOMS	.	.	.	1	0.8	1	2	1.6	2
	DIZZINESS	25	19.5	36	7	5.5	9	2	1.6	2
	DRUG DEPENDENCE	.	.	.	.	.	.	1	0.8	1
	EMOTIONAL LABILITY	1	0.8	1	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Nervous	HOSTILITY	.	.	.	.	.	.	1	0.8	1
	HYPERTONIA	2	1.6	2	2	1.6	2	.	.	.
	HYPESTHESIA	1	0.8	1	1	0.8	1	.	.	.
	INSOMNIA	26	20.3	30	31	24.2	32	8	6.3	9
	LIBIDO DECREASED	1	0.8	1	1	0.8	1	.	.	.
	MANIC SYMPTOMS	1	0.8	1	2	1.6	2	.	.	.
	MUSCLE CRAMP	2	1.6	4	.	.	.	.	.	.
	NERVOUSNESS	3	2.3	3	8	6.3	8	2	1.6	2
	NIGHTMARES	1	0.8	1	2	1.6	2	.	.	.
	PARASOMNIA NOS	.	.	.	1	0.8	1	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Nervous	PARESTHESIA	10	7.8	12	1	0.8	3	.	.	.
	RESTLESSNESS	2	1.6	2	.	.	.	.	.	.
	SCIATICA NOS	.	.	.	.	.	.	1	0.8	1
	SOMNILOQUISM	1	0.8	1	.	.	.	.	.	.
	SOMNOLENCE	7	5.5	11	4	3.1	5	3	2.3	3
	SUICIDAL TENDENCY	.	.	.	.	.	.	2	1.6	2
	TREMOR	3	2.3	3	.	.	.	.	.	.
Respiratory	ASTHMA	1	0.8	1	.	.	.	.	.	.
	BRONCHITIS	1	0.8	1	2	1.6	3	.	.	.
	CONGESTION CHEST	1	0.8	1	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Respiratory	COUGH	1	0.8	1	.	.	.	.	.	.
	DYSPNEA	2	1.6	2	.	.	.	.	.	.
	EPISTAXIS	1	0.8	1	.	.	.	.	.	.
	PHARYNGITIS	4	3.1	4	.	.	.	.	.	.
	RHINITIS	7	5.5	11	1	0.8	1	.	.	.
	SINUSITIS	2	1.6	2	5	3.9	5	1	0.8	1
Skin	DERMATITIS	1	0.8	1	.	.	.	.	.	.
	DIAPHORETIC	19	14.8	22	16	12.5	17	2	1.6	2
	DISORDER HAIR	.	.	.	1	0.8	1	.	.	.
	DISORDER SKIN NEC	.	.	.	1	0.8	1	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Skin	DRY SKIN NON-APPLICATION SITE	1	0.8	1	.	.	.	.	.	.
	ECZEMA	.	.	.	1	0.8	1	.	.	.
	ERYTHEMA	1	0.8	2	.	.	.	.	.	.
	HAIR LOSS	1	0.8	1	.	.	.	.	.	.
	HERPES SIMPLEX DERM	2	1.6	2	.	.	.	.	.	.
	NODULE SKIN	1	0.8	1	.	.	.	.	.	.
	PRURITUS NON-APPLICATION SITE	2	1.6	5	.	.	.	.	.	.
	RASH	5	3.9	6	.	.	.	.	.	.
	SKIN EROSION NEC	1	0.8	1	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Special Senses	BLURRED VISION	4	3.1	4	2	1.6	2	.	.	.
	DISORDER EYE	1	0.8	1	.	.	.	.	.	.
	DISORDER LACRIMATION	1	0.8	1	.	.	.	.	.	.
	DRY EYES	1	0.8	1	.	.	.	.	.	.
	EAR PAIN	.	.	.	1	0.8	1	.	.	.
	EYE IRRITATION	1	0.8	1	.	.	.	.	.	.
	EYE PAIN	1	0.8	1	.	.	.	.	.	.
	TASTE PERVERSION	6	4.7	6	2	1.6	2	.	.	.
	TINNITUS	4	3.1	4	1	0.8	1	.	.	.
Urogenital	BREAST PAIN	1	0.8	1	.	.	.	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Urogenital	DISORDER MENSTRUAL NEC	2	1.6	2	.	.	.	.	.	.
	DISORDER TESTICLE	1	0.8	1	1	0.8	1	.	.	.
	DISORDER URETHRAL	.	.	.	1	0.8	1	.	.	.
	DISORDER VULVOVAGINAL	1	0.8	1	1	0.8	1	.	.	.
	DYSMENORRHEA	.	.	.	1	0.8	1	.	.	.
	DYSURIA	1	0.8	1	2	1.6	3	1	0.8	1
	EJACULATION ABNORMAL	8	6.3	9	1	0.8	1	.	.	.
	FREQUENCY URINARY	1	0.8	1	.	.	.	.	.	.
	IMPOTENCE	3	2.3	3	3	2.3	3	1	0.8	1
	INFECTION URINARY TRACT	2	1.6	2	1	0.8	1	.	.	.

(CONTINUED)

Table AE11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase -
Frequency by Maximun Severity, Body System and COSTART Term, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients ---(N=128)								
		Mild			Moderate			Severe		
		n	%	# of Events	n	%	# of Events	n	%	# of Events
Urogenital	MENOPAUSE	.	.	.	1	0.8	1	.	.	.
	NOCTURIA	1	0.8	1	.	.	.	.	.	.
	OLIGURIA	1	0.8	1	.	.	.	.	.	.
	PAIN TESTICULAR	1	0.8	1	.	.	.	.	.	.
	POLYURIA	1	0.8	1	.	.	.	.	.	.
	PYELONEPHRITIS	.	.	.	1	0.8	1	.	.	.
	RETENTION URINARY	2	1.6	2	3	2.3	3	1	0.8	1
	SEXUAL FUNCTION ABNORMAL	.	.	.	2	1.6	2	.	.	.
	URGENCY URINATION	1	0.8	1	1	0.8	1	.	.	.
	URINATION IMPAIRED	12	9.4	12	4	3.1	4	1	0.8	1

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
No of AE reported				278			752
Patients with at least one AE		40	97.6		85	97.7	
Body	ABDOMINAL CRAMP	1	2.4	1	6	6.9	7
	ABDOMINAL DISTENSION	1	2.4	1	6	6.9	6
	ABDOMINAL PAIN GENERALIZED				1	1.1	2
	ABDOMINAL PAIN LOCALIZED	1	2.4	1	1	1.1	1
	ALLERGIC REACTION	2	4.9	2	2	2.3	2
	ASTHENIA				6	6.9	6
	BACK PAIN	5	12.2	5	11	12.6	13
	CHEST PAIN	1	2.4	2	4	4.6	5

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Body	CHILLS	7	17.1	9	11	12.6	13
	ENVIRONMENTAL ALLERGY	2	4.9	3	1	1.1	1
	FATIGUE	1	2.4	1	6	6.9	16
	FEVER	1	2.4	1	1	1.1	1
	FLU SYNDROME	3	7.3	3	4	4.6	4
	GENERALIZED EDEMA	1	2.4	1	3	3.4	3
	GENERALIZED PAIN				1	1.1	2
	HANGOVER				1	1.1	1
	HEADACHE	15	36.6	21	46	52.9	86
	INFECTION FUNGAL NOS				1	1.1	1
	LOCALIZED EDEMA				1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Body	LOCALIZED PAIN	4	9.8	4	8	9.2	8
	NECK PAIN				3	3.4	5
	NECK RIGID	1	2.4	1			
	NON-GENERALIZED WEAKNESS NOS				2	2.3	4
	REACTION UNEVALUABLE	1	2.4	1	8	9.2	12
	SUICIDE ATTEMPT				1	1.1	1
	TRAUMA	1	2.4	1	11	12.6	13
	UPPER RESPIRATORY INFECTION	2	4.9	2	15	17.2	17
Cardiovascular	DISORDER PERIPHERAL VASCULAR	2	4.9	3	1	1.1	1
	HYPERTENSION				2	2.3	2

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Cardiovascular	HYPOTENSION	1	2.4	1			
	HYPOTENSION POSTURAL	3	7.3	3	1	1.1	1
	MIGRAINE	1	2.4	1	2	2.3	2
	PALPITATION	3	7.3	3	5	5.7	5
	SINUS TACHYCARDIA				1	1.1	1
	TACHYCARDIA	1	2.4	1	4	4.6	4
	VASODILATION	4	9.8	5	16	18.4	21
Digestive	APPETITE DECREASED	3	7.3	3	12	13.8	12
	APPETITE INCREASED				3	3.4	8
	CONSTIPATION	9	22.0	11	27	31.0	29
	DIARRHEA	3	7.3	3	5	5.7	5

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Digestive	DISORDER RECTAL				1	1.1	1
	DISORDER TONGUE				1	1.1	2
	DRY MOUTH	14	34.1	16	42	48.3	49
	DYSPEPSIA	6	14.6	9	13	14.9	15
	FLATULENCE	1	2.4	1	3	3.4	3
	GASTRITIS	1	2.4	1			
	GASTROENTERITIS	1	2.4	1	2	2.3	2
	GASTROINTESTINAL BLEEDING				1	1.1	1
	GINGIVITIS	1	2.4	1			
	HEMORRHOID	1	2.4	1	1	1.1	1
	INCREASED THIRST				2	2.3	2

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Digestive	LOOSE STOOLS NEC				2	2.3	2
	NAUSEA	7	17.1	7	19	21.8	29
	RECTAL BLEEDING				1	1.1	1
	STOMATITIS APHTHOUS				1	1.1	1
	THROAT DRY				1	1.1	1
	TOOTH ABSCESS	1	2.4	1			
	TOOTHACHE	1	2.4	1	1	1.1	1
	ULCER MOUTH				1	1.1	1
	VOMITING	1	2.4	1	3	3.4	3
Hemic and Lymphatic	ECCHYMOSIS/BRUISE				1	1.1	1
Metabolic and Nutritional	BILIRUBINEMIA	1	2.4	1			

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Metabolic and Nutritional	HYPERCHOLESTEREMIA	1	2.4	1			
	PERIPHERAL EDEMA				3	3.4	3
	WEIGHT DECREASE	1	2.4	1			
	WEIGHT INCREASE	1	2.4	1	1	1.1	2
Musculo-Skeletal	CARPAL TUNNEL SYNDROME				1	1.1	1
	CRAMP LEGS	2	4.9	2	4	4.6	6
	JOINT STIFFNESS				1	1.1	1
	MUSCULAR WEAKNESS				1	1.1	2
	MYALGIA				6	6.9	6
Nervous	AGITATION	1	2.4	1	2	2.3	3
	AKATHISIA				1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Nervous	AMNESIA				1	1.1	2
	ANXIETY	4	9.8	4	10	11.5	12
	ATAXIA				1	1.1	1
	CHANGE IN DREAMS	1	2.4	1	7	8.0	9
	CNS STIMULATION				1	1.1	1
	CONCENTRATION IMPAIRED				4	4.6	4
	CONFUSION	1	2.4	1	1	1.1	1
	DEPRESSIVE SYMPTOMS	1	2.4	1	2	2.3	2
	DIZZINESS	6	14.6	9	26	29.9	38
	DRUG DEPENDENCE				1	1.1	1
	EMOTIONAL LABILITY	1	2.4	1			

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Nervous	HOSTILITY	1	2.4	1			
	HYPERTONIA				4	4.6	4
	HYPESTHESIA				1	1.1	2
	INSOMNIA	18	43.9	21	43	49.4	50
	LIBIDO DECREASED	2	4.9	2			
	MANIC SYMPTOMS				3	3.4	3
	MUSCLE CRAMP				2	2.3	4
	NERVOUSNESS	1	2.4	1	12	13.8	12
	NIGHTMARES				3	3.4	3
	PARASOMNIA NOS				1	1.1	1
	PARESTHESIA	4	9.8	6	7	8.0	9

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Nervous	RESTLESSNESS	1	2.4	1	1	1.1	1
	SCIATICA NOS				1	1.1	1
	SOMNILOQUISM				1	1.1	1
	SOMNOLENCE	4	9.8	4	10	11.5	15
	SUICIDAL TENDENCY				2	2.3	2
	TREMOR	1	2.4	1	2	2.3	2
Respiratory	ASTHMA				1	1.1	1
	BRONCHITIS				3	3.4	4
	CONGESTION CHEST	1	2.4	1			
	COUGH				1	1.1	1
	DYSPNEA	1	2.4	1	1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Respiratory	EPISTAXIS				1	1.1	1
	PHARYNGITIS	1	2.4	1	3	3.4	3
	RHINITIS	3	7.3	6	4	4.6	6
	SINUSITIS	3	7.3	3	5	5.7	5
Skin	DERMATITIS				1	1.1	1
	DIAPHORETIC	10	24.4	12	24	27.6	29
	DISORDER HAIR				1	1.1	1
	DISORDER SKIN NEC				1	1.1	1
	DRY SKIN NON-APPLICATION SITE				1	1.1	1
	ECZEMA				1	1.1	1
	ERYTHEMA				1	1.1	2

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Skin	HAIR LOSS				1	1.1	1
	HERPES SIMPLEX DERM				2	2.3	2
	NODULE SKIN				1	1.1	1
	PRURITUS NON-APPLICATION SITE				2	2.3	5
	RASH	2	4.9	2	3	3.4	4
	SKIN EROSION NEC				1	1.1	1
Special Senses	BLURRED VISION				6	6.9	6
	DISORDER EYE				1	1.1	1
	DISORDER LACRIMATION	1	2.4	1			
	DRY EYES	1	2.4	1			
	EAR PAIN				1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Special Senses	EYE IRRITATION				1	1.1	1
	EYE PAIN				1	1.1	1
	TASTE PERVERSION	2	4.9	2	6	6.9	6
	TINNITUS	2	4.9	2	3	3.4	3
Urogenital	BREAST PAIN				1	1.1	1
	DISORDER MENSTRUAL NEC				2	2.3	2
	DISORDER TESTICLE	2	4.9	2			
	DISORDER URETHRAL	1	2.4	1			
	DISORDER VULVOVAGINAL				2	2.3	2
	DYSMENORRHEA				1	1.1	1
	DYSURIA	3	7.3	4	1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Urogenital	EJACULATION ABNORMAL	9	22.0	10			
	FREQUENCY URINARY	1	2.4	1			
	IMPOTENCE	7	17.1	7			
	INFECTION URINARY TRACT				3	3.4	3
	MENOPAUSE				1	1.1	1
	NOCTURIA	1	2.4	1			
	OLIGURIA				1	1.1	1
	PAIN TESTICULAR	1	2.4	1			
	POLYURIA	1	2.4	1			
	PYELONEPHRITIS				1	1.1	1
	RETENTION URINARY	4	9.8	5	1	1.1	1

(CONTINUED)

Table AE12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events Reported in the Open Phase - Frequency by Gender, Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	Male (N=41)			Female (N=87)		
		n	%	# of Events	n	%	# of Events
Urogenital	SEXUAL FUNCTION ABNORMAL	2	4.9	2			
	URGENCY URINATION	2	4.9	2			
	URINATION IMPAIRED	14	34.1	14	3	3.4	3

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				784
Patients with at least one AE		124	96.9	
Body	ABDOMINAL CRAMP	6	4.7	6
	ABDOMINAL DISTENSION	5	3.9	5
	ABDOMINAL PAIN GENERALIZED	1	0.8	1
	ABDOMINAL PAIN LOCALIZED	2	1.6	2
	ALLERGIC REACTION	2	1.6	2
	ASTHENIA	5	3.9	5
	BACK PAIN	10	7.8	11
	CHEST PAIN	4	3.1	5

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	CHILLS	16	12.5	19
	ENVIRONMENTAL ALLERGY	1	0.8	2
	FATIGUE	6	4.7	7
	FEVER	2	1.6	2
	FLU SYNDROME	5	3.9	5
	GENERALIZED EDEMA	2	1.6	2
	GENERALIZED PAIN	1	0.8	2
	HANGOVER	1	0.8	1
	HEADACHE	52	40.6	75
	INFECTION FUNGAL NOS	1	0.8	1
	LOCALIZED EDEMA	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	LOCALIZED PAIN	10	7.8	10
	NECK PAIN	2	1.6	3
	NECK RIGID	1	0.8	1
	NON-GENERALIZED WEAKNESS NOS	2	1.6	2
	REACTION UNEVALUABLE	6	4.7	7
	SUICIDE ATTEMPT	1	0.8	1
	TRAUMA	5	3.9	6
	UPPER RESPIRATORY INFECTION	11	8.6	11
Cardiovascular	DISORDER PERIPHERAL VASCULAR	3	2.3	4
	HYPOTENSION	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Cardiovascular	HYPOTENSION POSTURAL	4	3.1	4
	MIGRAINE	1	0.8	1
	PALPITATION	7	5.5	7
	SINUS TACHYCARDIA	1	0.8	1
	TACHYCARDIA	4	3.1	4
	VASODILATION	15	11.7	19
Digestive	APPETITE DECREASED	14	10.9	14
	APPETITE INCREASED	3	2.3	4
	CONSTIPATION	31	24.2	32
	DIARRHEA	6	4.7	6
	DISORDER RECTAL	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	DISORDER TONGUE	1	0.8	2
	DRY MOUTH	51	39.8	55
	DYSPEPSIA	16	12.5	17
	FLATULENCE	2	1.6	2
	GASTRITIS	1	0.8	1
	GASTROENTERITIS	2	1.6	2
	GASTROINTESTINAL BLEEDING	1	0.8	1
	GINGIVITIS	1	0.8	1
	HEMORRHOID	2	1.6	2
	INCREASED THIRST	2	1.6	2
	LOOSE STOOLS NEC	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	NAUSEA	23	18.0	30
	RECTAL BLEEDING	1	0.8	1
	STOMATITIS APHTHOUS	1	0.8	1
	THROAT DRY	1	0.8	1
	TOOTH ABSCESS	1	0.8	1
	ULCER MOUTH	1	0.8	1
	VOMITING	3	2.3	3
Hemic and Lymphatic	ECCHYMOSIS/BRUISE	1	0.8	1
Metabolic and Nutritional	PERIPHERAL EDEMA	1	0.8	1
	WEIGHT DECREASE	1	0.8	1
	WEIGHT INCREASE	2	1.6	2

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Musculo-Skeletal	CARPAL TUNNEL SYNDROME	1	0.8	1
	CRAMP LEGS	3	2.3	4
	JOINT STIFFNESS	1	0.8	1
	MUSCULAR WEAKNESS	1	0.8	2
	MYALGIA	3	2.3	3
Nervous	AGITATION	3	2.3	4
	AMNESIA	1	0.8	2
	ANXIETY	12	9.4	14
	ATAXIA	1	0.8	1
	CHANGE IN DREAMS	8	6.3	9
	CNS STIMULATION	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	CONCENTRATION IMPAIRED	3	2.3	3
	CONFUSION	1	0.8	1
	DEPRESSIVE SYMPTOMS	3	2.3	3
	DIZZINESS	24	18.8	35
	DRUG DEPENDENCE	1	0.8	1
	HOSTILITY	1	0.8	1
	HYPERTONIA	3	2.3	3
	HYPESTHESIA	1	0.8	2
	INSOMNIA	53	41.4	60
	LIBIDO DECREASED	2	1.6	2
	MANIC SYMPTOMS	3	2.3	3

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	MUSCLE CRAMP	2	1.6	2
	NERVOUSNESS	11	8.6	11
	NIGHTMARES	2	1.6	2
	PARASOMNIA NOS	1	0.8	1
	PARESTHESIA	10	7.8	13
	RESTLESSNESS	2	1.6	2
	SCIATICA NOS	1	0.8	1
	SOMNILOQUISM	1	0.8	1
	SOMNOLENCE	12	9.4	13
	SUICIDAL TENDENCY	2	1.6	2
	TREMOR	3	2.3	3

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Respiratory	ASTHMA	1	0.8	1
	BRONCHITIS	2	1.6	3
	COUGH	1	0.8	1
	DYSPNEA	2	1.6	2
	PHARYNGITIS	4	3.1	4
	RHINITIS	6	4.7	7
	SINUSITIS	6	4.7	6
Skin	DIAPHORETIC	31	24.2	35
	DISORDER HAIR	1	0.8	1
	DISORDER SKIN NEC	1	0.8	1
	ECZEMA	1	0.8	1

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Skin	HAIR LOSS	1	0.8	1
	HERPES SIMPLEX DERM	1	0.8	1
	PRURITUS NON-APPLICATION SITE	2	1.6	5
	RASH	2	1.6	3
	SKIN EROSION NEC	1	0.8	1
Special Senses	BLURRED VISION	6	4.7	6
	DISORDER EYE	1	0.8	1
	DISORDER LACRIMATION	1	0.8	1
	EYE IRRITATION	1	0.8	1
	EYE PAIN	1	0.8	1
	TASTE PERVERSION	6	4.7	6

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Special Senses	TINNITUS	3	2.3	3
Urogenital	BREAST PAIN	1	0.8	1
	DISORDER MENSTRUAL NEC	2	1.6	2
	DISORDER TESTICLE	2	1.6	2
	DISORDER URETHRAL	1	0.8	1
	DISORDER VULVOVAGINAL	2	1.6	2
	DYSMENORRHEA	1	0.8	1
	DYSURIA	4	3.1	5
	EJACULATION ABNORMAL	8	6.3	9
	IMPOTENCE	6	4.7	6
	INFECTION URINARY TRACT	3	2.3	3

(CONTINUED)

Table AE13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started within Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	MENOPAUSE	1	0.8	1
	NOCTURIA	1	0.8	1
	OLIGURIA	1	0.8	1
	PAIN TESTICULAR	1	0.8	1
	POLYURIA	1	0.8	1
	RETENTION URINARY	5	3.9	5
	SEXUAL FUNCTION ABNORMAL	2	1.6	2
	URGENCY URINATION	2	1.6	2
	URINATION IMPAIRED	17	13.3	17

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
No of AE reported				241
Patients with at least one AE		73	57.0	
Body	ABDOMINAL CRAMP	2	1.6	2
	ABDOMINAL DISTENSION	2	1.6	2
	ABDOMINAL PAIN GENERALIZED	1	0.8	1
	ALLERGIC REACTION	2	1.6	2
	ASTHENIA	1	0.8	1
	BACK PAIN	7	5.5	7
	CHEST PAIN	2	1.6	2
	CHILLS	2	1.6	3

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	ENVIRONMENTAL ALLERGY	2	1.6	2
	FATIGUE	2	1.6	10
	FLU SYNDROME	2	1.6	2
	GENERALIZED EDEMA	2	1.6	2
	HEADACHE	22	17.2	32
	LOCALIZED PAIN	2	1.6	2
	NECK PAIN	2	1.6	2
	NON-GENERALIZED WEAKNESS NOS	1	0.8	2
	REACTION UNEVALUABLE	4	3.1	6
	TRAUMA	6	4.7	7

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Body	UPPER RESPIRATORY INFECTION	7	5.5	8
Cardiovascular	HYPERTENSION	2	1.6	2
	MIGRAINE	2	1.6	2
	PALPITATION	1	0.8	1
	TACHYCARDIA	1	0.8	1
	VASODILATION	6	4.7	7
Digestive	APPETITE DECREASED	1	0.8	1
	APPETITE INCREASED	1	0.8	4
	CONSTIPATION	7	5.5	8
	DIARRHEA	2	1.6	2
	DRY MOUTH	8	6.3	8

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Digestive	DYSPEPSIA	5	3.9	7
	FLATULENCE	2	1.6	2
	GASTROENTERITIS	1	0.8	1
	LOOSE STOOLS NEC	1	0.8	1
	NAUSEA	6	4.7	6
	TOOTHACHE	2	1.6	2
	VOMITING	1	0.8	1
Metabolic and Nutritional	BILIRUBINEMIA	1	0.8	1
	HYPERCHOLESTEREMIA	1	0.8	1
	PERIPHERAL EDEMA	2	1.6	2
	WEIGHT INCREASE	1	0.8	1

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Musculo-Skeletal	CRAMP LEGS	4	3.1	4
	MYALGIA	3	2.3	3
Nervous	AKATHISIA	1	0.8	1
	ANXIETY	2	1.6	2
	CHANGE IN DREAMS	1	0.8	1
	CONCENTRATION IMPAIRED	1	0.8	1
	CONFUSION	1	0.8	1
	DIZZINESS	11	8.6	12
	EMOTIONAL LABILITY	1	0.8	1
	HYPERTONIA	1	0.8	1
	INSOMNIA	8	6.3	9

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Nervous	MUSCLE CRAMP	1	0.8	2
	NERVOUSNESS	2	1.6	2
	NIGHTMARES	1	0.8	1
	PARESTHESIA	2	1.6	2
	SOMNOLENCE	3	2.3	6
Respiratory	BRONCHITIS	1	0.8	1
	CONGESTION CHEST	1	0.8	1
	EPISTAXIS	1	0.8	1
	RHINITIS	4	3.1	5
	SINUSITIS	2	1.6	2
Skin	DERMATITIS	1	0.8	1

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Skin	DIAPHORETIC	5	3.9	6
	DRY SKIN NON-APPLICATION SITE	1	0.8	1
	ERYTHEMA	1	0.8	2
	HERPES SIMPLEX DERM	1	0.8	1
	NODULE SKIN	1	0.8	1
	RASH	3	2.3	3
Special Senses	DRY EYES	1	0.8	1
	EAR PAIN	1	0.8	1
	TASTE PERVERSION	2	1.6	2
	TINNITUS	2	1.6	2
Urogenital	EJACULATION ABNORMAL	1	0.8	1

(CONTINUED)

Table AE14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events that Started after Four Weeks of Treatment, Open Label Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	--- Patients --- (N=128)		# of Reports
		n	%	
Urogenital	FREQUENCY URINARY	1	0.8	1
	IMPOTENCE	1	0.8	1
	PYELONEPHRITIS	1	0.8	1
	RETENTION URINARY	1	0.8	1

Table AE15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System
All Enrolled Patients

Date Produced: January 15, 2001

Body System	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
	n	%	# of Reports	n	%	# of Reports
No of AE reported			61			60
Patients with at least one AE	19	79.2		15	68.2	
Body	15	62.5	25	12	54.5	31
Cardiovascular	2	8.3	2	1	4.5	1
Digestive	4	16.7	5	4	18.2	5
Metabolic and Nutritional	1	4.2	1			
Musculo-Skeletal	3	12.5	5	3	13.6	7
Nervous	9	37.5	13	5	22.7	6
Respiratory	2	8.3	2	5	22.7	7
Skin	1	4.2	1			
Special Senses	4	16.7	4	1	4.5	1

(CONTINUED)

Table AE15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System
All Enrolled Patients

Date Produced: January 15, 2001

Body System	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
	n	%	# of Reports	n	%	# of Reports
Urogenital	3	12.5	3	2	9.1	2

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
No of AE reported				61			60
Patients with at least one AE		19	79.2		15	68.2	
Body	ABDOMINAL PAIN LOCALIZED	2	8.3	2	2	9.1	2
	ALLERGIC REACTION	1	4.2	1			
	ASTHENIA	1	4.2	1			
	BACK PAIN				2	9.1	2
	CHEST PAIN	1	4.2	1			
	ENVIRONMENTAL ALLERGY	1	4.2	1			
	FATIGUE	2	8.3	3	1	4.5	1
	FEVER	2	8.3	2			

(CONTINUED)

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
Body	FLU SYNDROME	1	4.2	1	2	9.1	2
	GENERALIZED EDEMA	1	4.2	1	1	4.5	1
	GENERALIZED PAIN				1	4.5	1
	HEADACHE	5	20.8	6	4	18.2	9
	INFECTION FUNGAL NOS				1	4.5	1
	LOCALIZED PAIN	2	8.3	4	4	18.2	5
	NECK RIGID				1	4.5	1
	PERIOPERATIVE EVENT				1	4.5	1
	UPPER RESPIRATORY INFECTION	2	8.3	2	3	13.6	5
Cardiovascular	HYPERTENSION	2	8.3	2			

(CONTINUED)

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
Cardiovascular	MIGRAINE				1	4.5	1
Digestive	DIARRHEA	1	4.2	1	1	4.5	1
	DRY MOUTH	1	4.2	1	1	4.5	1
	DYSPEPSIA				1	4.5	1
	GASTROENTERITIS	1	4.2	1			
	GUM INFECTION	1	4.2	1			
	NAUSEA	1	4.2	1	1	4.5	1
	TOOTHACHE				1	4.5	1
Metabolic and Nutritional	PERIPHERAL EDEMA	1	4.2	1			
Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	1	4.2	3			

(CONTINUED)

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
Musculo-Skeletal	CRAMP LEGS	1	4.2	1			
	DISORDER JOINT	1	4.2	1			
	DISORDER TENDON				1	4.5	1
	MYALGIA				3	13.6	6
Nervous	CHANGE IN DREAMS	1	4.2	1			
	CONFUSION	1	4.2	1			
	DIZZINESS				4	18.2	4
	INSOMNIA				2	9.1	2
	LIBIDO DECREASED	1	4.2	1			
	NEOPLASM CNS	1	4.2	1			
	NERVOUSNESS	2	8.3	2			

(CONTINUED)

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
Nervous	PARESTHESIA	4	16.7	5			
	RESTLESSNESS	1	4.2	1			
	SOMNOLENCE	1	4.2	1			
Respiratory	COUGH				1	4.5	1
	PHARYNGITIS	1	4.2	1	2	9.1	2
	RHINITIS	1	4.2	1	1	4.5	1
	SINUSITIS				2	9.1	3
Skin	PRURITUS NON-APPLICATION SITE	1	4.2	1			
Special Senses	BLURRED VISION	2	8.3	2			
	TINNITUS	2	8.3	2			

(CONTINUED)

Table AE16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Treatment Emergent Adverse Events that Started in the Blinded Phase - Frequency by Body System and COSTART Term
All Enrolled Patients

Date Produced: January 15, 2001

Body System	COSTART Term	----- Reboxetine ----- (N=24)			------ Placebo ------- (N=22)		
		n	%	# of Reports	n	%	# of Reports
Special Senses	VISION ABNORMAL				1	4.5	1
Urogenital	CARCINOMA BLADDER				1	4.5	1
	EJACULATION ABNORMAL	1	4.2	1			
	IMPOTENCE	1	4.2	1			
	INFECTION URINARY TRACT				1	4.5	1
	RETENTION URINARY	1	4.2	1			

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
RBX	Amsterdam	11066	56/M	Body	ABDOMINAL PAIN LOCALIZED	STOMACH PAIN	68	.	80	No	Moderate	Yes	Not recovered	.
	Croft	231001	50/F	Body	CHEST PAIN	CHEST PAIN	97	11	128	No	Mild	No	Recovered	.
					HEADACHE	HEADACHE	71	1	128	No	Moderate	No	Recovered	.
				Cardiovascular	HYPERTENSION	ELEVATED BLOOD PRESSURE	70	.	128	No	Mild	No	Not recovered	.
				Nervous	NERVOUSNESS	INCREASED NERVOUSNESS	109	4	128	No	Mild	No	Recovered	.
		231079	65/M	Urogenital	RETENTION URINARY	URINE RETENTION	66	9	136	No	Mild	Yes	Recovered	.
	Delgado	41069	41/F	Body	FEVER	FEVER	61	1	71	No	Mild	No	Recovered	.
				Metabolic and Nutritional	PERIPHERAL EDEMA	BILATERAL ANKLE EDEMA	63	.	71	No	Mild	Yes	Not recovered	PT. SAW HER PCP AND HE ADVISES THAT HER SX'S COULD BE A VIRAL INFECTION
				Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	BILATERAL ANKLE JOINT PAIN	58	.	71	No	Mild	Yes	Not recovered	.
						BILATERAL KNEE JOINT PAIN	58	.	71	No	Mild	Yes	Not recovered	.
						JOINT PAIN (BILATERAL WRIST)	58	.	71	No	Mild	Yes	Not recovered	.
		41093	56/F	Body	FATIGUE	FATIGUE	60	1	72	No	Mild	No	Recovered	.
							63	5	72	No	Mild	No	Recovered	.
				Nervous	CONFUSION	CONFUSION	61	2	72	No	Moderate	Yes	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
RBX	DuBoff	311017	54/M	Body	LOCALIZED PAIN	SHOULDER PAIN	74	1	99	No	Moderate	No	Recovered	.
							81	.	99	No	Moderate	No	Not recovered	.
				Nervous	PARESTHESIA	PARESTHESIA FINGER TIPS	78	.	99	No	Moderate	Yes	Not recovered	.
					SOMNOLENCE	AM SEDATION	62	.	99	No	Moderate	Yes	Not recovered	.
	Dunner	211040	53/F	Nervous	CHANGE IN DREAMS	STRANGE DREAMS	59	.	79	No	Mild	Yes	Not recovered	.
					PARESTHESIA	TINGLING IN RT. ARM	62	.	79	No	Mild	No	Not recovered	.
		211109	43/M	Body	HEADACHE	HEADACHE	62	11	78	No	Moderate	Yes	Recovered	.
	Helfing	81075	37/F	Body	FLU SYNDROME	FLU SYMPTOMS	82	2	167	No	Moderate	No	Recovered	.
					UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	109	4	167	No	Moderate	No	Recovered	.
				Cardiovascular	HYPERTENSION	INCREASED BLOOD PRESSURE	166	.	167	No	Mild	Yes	Not recovered	.
		81076	23/F	Body	HEADACHE	HEADACHE	61	1	171	No	Moderate	Yes	Recovered	.
					UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	63	3	171	No	Mild	No	Recovered	.
				Digestive	GASTROENTERITIS	VIRAL GASTROENTERITIS	81	5	171	No	Moderate	No	Recovered	.
					GUM INFECTION	GUM INFECTION	135	6	171	No	Moderate	No	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
RBX	Helfing	81076	23/F	Musculo-Skeletal	DISORDER JOINT	DISLOCATED 2 RIBS - LEFT SIDE	98	36	171	No	Moderate	No	Recovered	.
	Hoopes	271022	42/F	Body	ALLERGIC REACTION	FLU SHOT REACTION	62	3	77	No	Moderate	No	Recovered	.
					HEADACHE	HEADACHE	69	.	77	No	Mild	Yes	Not recovered	.
				Special Senses	TINNITUS	TINNITUS	75	.	77	No	Mild	Yes	Not recovered	.
	Lydiard	221033	44/M	Body	ASTHENIA	WEAKNESS	63	2	141	No	Moderate	Yes	Recovered	.
				Special Senses	BLURRED VISION	FOCUSING DIFFICULTY	63	2	141	No	Moderate	Yes	Recovered	.
	Moreines	121007	33/F	Nervous	NERVOUSNESS	IRRITABILITY	71	.	93	No	Severe	Yes	Not recovered	.
				Skin	PRURITUS NON-APPLICATION SITE	ITCHING ON L ARM	69	24	93	No	Mild	Yes	Recovered	.
	Oldroyd	321087	55/M	Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS	110	1	171	No	Moderate	No	Recovered	.
	Prover	261023	33/F	Body	ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	133	6	.	No	Mild	No	Recovered	.
					FATIGUE	FATIGUE	97	1	.	No	Moderate	No	Recovered	.
					FEVER	FEVER (INTERMITTENT)	95	3	.	No	Mild	No	Recovered	.
				Digestive	NAUSEA	NAUSEA	133	6	.	No	Mild	No	Recovered	.
				Respiratory	PHARYNGITIS	SORE THROAT	95	5	.	No	Moderate	No	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
RBX	Rapaport	151095	49/M	Body	GENERALIZED EDEMA	EDEMA	70	.	156	No	Mild	Yes	Not recovered	.
				Nervous	PARESTHESIA	TINGLING (RIGHT SIDE OF FACE)	107	.	156	No	Mild	Yes	Not recovered	.
				Special Senses	BLURRED VISION	BLURRED VISION	90	10	156	No	Mild	Yes	Recovered	.
	Thase	181083	58/M	Body	ENVIRONMENTAL ALLERGY	SEASONAL ALLERGY SYMPTOMS	110	.	143	No	Mild	No	Not recovered	.
				Digestive	DIARRHEA	DIARRHEA	91	1	143	No	Mild	No	Recovered	.
				Nervous	LIBIDO DECREASED	DIMINISHED LIBIDO	90	.	143	No	Mild	Yes	Not recovered	.
				Respiratory	RHINITIS	POST NASAL DRIP	74	31	143	No	Mild	No	Recovered	.
				Special Senses	TINNITUS	DIMINISHED OCCURRENCE OF TINNITUS FROM BASELINE	107	.	143	No	Mild	Yes	Not recovered	.
				Urogenital	IMPOTENCE	ERECTILE DIFFICULTY-OBTAINING, MAINTAINING	119	.	143	No	Mild	Yes	Not recovered	.
	Trivedi	191014	47/M	Body	HEADACHE	HEADACHE	68	1	156	No	Mild	No	Recovered	.
							85	1	156	No	Mild	No	Recovered	.
				Digestive	DRY MOUTH	DRY MOUTH	72	53	156	No	Mild	No	Recovered	.
				Nervous	NEOPLASM CNS	BRAIN TUMOR	159	.	156	Yes	Severe	No	Unknown	.
					PARESTHESIA	TINGLING SCALP	89	1	156	No	Mild	No	Recovered	.
				Urogenital	EJACULATION ABNORMAL	PREMATURE EJACULATION	89	.	156	No	Mild	No	Unknown	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
RBX	Zajecka	201067	31/M	Body	LOCALIZED PAIN	PAIN IN RIGHT GROIN AREA	67	14	120	No	Mild	No	Recovered	.
				Nervous	RESTLESSNESS	RESTLESSNESS	82	19	120	No	Mild	Yes	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
Placebo	DuBoff	311115	30/F	Body	FATIGUE	FATIGUE	79	5	113	No	Mild	Yes	Recovered	.
				Nervous	DIZZINESS	DIZZINESS	57	8	113	No	Mild	Yes	Recovered	.
	Dunner	211110	54/F	Nervous	INSOMNIA	INSOMNIA	66	1	78	No	Moderate	No	Recovered	.
	Helfing	81004	43/F	Body	HEADACHE	HEADACHE	56	1	78	No	Mild	Yes	Recovered	.
							58	1	78	No	Mild	Yes	Recovered	.
							66	1	78	No	Mild	Yes	Recovered	.
							69	1	78	No	Mild	Yes	Recovered	.
							75	1	78	No	Mild	Yes	Recovered	.
	Londborg	101044	41/F	Body	ABDOMINAL PAIN	STOMACH PAIN	71	10	211	No	Mild	Yes	Recovered	.
					LOCALIZED INFECTION	YEAST INFECTION	65	16	211	No	Mild	No	Recovered	.
					FUNGAL NOS									
					UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	171	6	211	No	Mild	No	Recovered	.
						VIRAL UPPER RESPIRATORY INFECTION	62	14	211	No	Mild	No	Recovered	.
				Digestive	DIARRHEA	DIARRHEA	83	1	211	No	Mild	Yes	Recovered	.
					TOOTHACHE	TOOTH ACHE	109	2	211	No	Mild	No	Recovered	.
				Nervous	DIZZINESS	DIZZINESS	57	4	211	No	Mild	Yes	Recovered	.
				Respiratory	PHARYNGITIS	SORE THROAT	171	6	211	No	Mild	No	Recovered	.
				Urogenital	INFECTION URINARY TRACT	URINARY TRACT INFECTION	199	15	211	No	Mild	No	Recovered	.
	Munjack	131011	56/M	Digestive	DRY MOUTH	DRY MOUTH	74	3	198	No	Mild	Yes	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
Placebo	Munjack	131011	56/M	Musculo-Skeletal	DISORDER TENDON	INFLAMED LIGAMENT AT BASE OF MIDDLE FINGER - R HAND	80	3	198	No	Moderate	No	Recovered	.
					MYALGIA	MYALAGIA - BACK	175	3	198	No	Moderate	No	Recovered	.
				Respiratory	SINUSITIS	SINUS INFECTION	86	4	198	No	Moderate	No	Recovered	.
							97	1	198	No	Mild	No	Recovered	.
		131012	42/F	Body	HEADACHE	HEADACHE	61	3	199	No	Severe	No	Recovered	.
					UPPER RESPIRATORY INFECTION	COLD SXS	78	1	199	No	Mild	No	Recovered	.
						COLD SYMPTOMS	64	1	199	No	Moderate	No	Recovered	.
				Cardiovascular	MIGRAINE	MIGRAINE HEADACHE	82	1	199	No	Severe	No	Recovered	.
		131125	34/F	Body	PERIOPERATIVE EVENT	POST-OP PAIN (L) BREAST	66	3	74	No	Moderate	No	Recovered	.
	Rapaport	151037	62/F	Body	ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	111	2	240	No	Mild	No	Recovered	.
					FLU SYNDROME	FLU	84	10	240	No	Mild	No	Recovered	.
					GENERALIZED EDEMA	EDEMA	73	27	240	No	Moderate	No	Recovered	.
					LOCALIZED PAIN	KNEE PROBLEMS (PAIN)	103	1	240	No	Moderate	No	Recovered	.
				Respiratory	SINUSITIS	SINUS INFECTION	70	18	240	No	Moderate	No	Recovered	.
				Special Senses	VISION ABNORMAL	VISUAL IMPAIRMENT (RIGHT EYE)	142	.	240	No	Moderate	No	Not recovered	.
		151038	52/M	Body	FLU SYNDROME	FLU	73	5	141	No	Mild	No	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
Placebo	Rapaport	151038	52/M	Body	UPPER RESPIRATORY INFECTION	COLD	73	5	141	No	Mild	No	Recovered	.
				Urogenital	CARCINOMA BLADDER	CANCER (BLADDER)	106	15	141	Yes	Severe	No	Recovered	.
	Smith	281102	44/F	Body	HEADACHE	HEADACHE	67	.	68	No	Mild	Yes	Not recovered	.
				Digestive	NAUSEA	NAUSEA	67	.	68	No	Mild	Yes	Not recovered	.
				Musculo-Skeletal	MYALGIA	MUSCLE ACHES	59	4	68	No	Mild	No	Recovered	.
							66	.	68	No	Mild	Yes	Not recovered	.
				Nervous	DIZZINESS	DIZZY	66	.	68	No	Mild	Yes	Not recovered	.
				Respiratory	COUGH	COUGH	59	.	68	No	Mild	No	Not recovered	.
					RHINITIS	NASAL CONGESTION	59	7	68	No	Mild	No	Recovered	.
		281108	53/F	Body	GENERALIZED PAIN	BODY ACHES	65	.	91	No	Mild	No	Not recovered	.
					LOCALIZED PAIN	RIGHT LEG ACHE	57	.	91	No	Mild	No	Not recovered	.
				Digestive	DYSPEPSIA	UPSET STOMACH	70	2	91	No	Mild	No	Recovered	.
				Respiratory	PHARYNGITIS	SORE THROAT	58	5	91	No	Mild	No	Recovered	.
	Telew	171015	45/F	Body	BACK PAIN	BACK ACHE	60	2	85	No	Mild	No	Recovered	.
	Thase	181084	32/M	Body	BACK PAIN	LOWER BACK PAIN	72	10	120	No	Mild	No	Recovered	.
				Musculo-Skeletal	MYALGIA	MUSCULAR PAINS	93	5	120	No	Moderate	No	Recovered	.
						MYALGIA, ARMS	67	15	120	No	Mild	No	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE16a

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Adverse Events that Started in the Blinded Phase
All Enrolled Patients

Date Produced: January 17, 2001

Treatment (RBX/ Placebo)	Inv. Name	Pat. Number	Age/ Sex	Body System	COSTART Term	Verbatim	Onset Day	Duration	Days on Study Med.	Serious	Maximun Intensity	Rel.	Outcome	Comment
Placebo	Thase	181084	32/M	Musculo-Skeletal	MYALGIA	MYALGIA, HANDS	67	15	120	No	Mild	No	Recovered	.
	Walsh	171015	45/F	Body	LOCALIZED PAIN	SORE SHOULDER	76	1	85	No	Mild	No	Recovered	.
					NECK RIGID	STIFF NECK	84	.	85	No	Mild	No	Not recovered	.
		171063	27/M	Body	HEADACHE	HEADACHE	63	1	88	No	Mild	No	Recovered	.
							79	1	88	No	Moderate	No	Recovered	.
					LOCALIZED PAIN	SHOULDER PAIN	79	2	88	No	Mild	No	Recovered	.
							85	2	88	No	Moderate	No	Recovered	.
	Zajecka	201068	37/F	Nervous	DIZZINESS	LIGHT HEADEDNESS	61	5	94	No	Mild	Yes	Recovered	.
					INSOMNIA	SLEEPLESSNESS	59	6	94	No	Mild	Yes	Recovered	.

Note: Onset day and stop day are relative to Baseline

Table AE17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Serious Adverse Events during Study
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Pat. No.	Age/Sex	Treatment Assigned in Blinded Phase	AE Verbatim	AE Onset Day	AE Duration	Days on Stdy Med.	Max. Intensity	Related to Study Medication	Action Taken	Outcome
Dunner	211147	37/Female		SUICIDE ATTEMPT	7	8	8	Severe	Yes	Drug permanently withdrawn	Recovered
Helfing	81052	39/Female		ALCOHOL RELAPSE	9	9	20	Severe	No	None	Recovered
Rapaport	151038	52/Male	Placebo	CANCER (BLADDER)	106	15	141	Severe	No	None	Recovered
Trivedi	191014	47/Male	RBX	BRAIN TUMOR	159		156	Severe	No	Drug permanently withdrawn	Unknown
Zajecka	201092	41/Female		SUICIDAL DEPRESSION	22	12	24	Severe	No	Drug permanently withdrawn	Recovered

Note: 1. Onset day is relative to Baseline.
2. Patient 191014 became chronic/stable after follow up (reported on Serious Adverse Event CRF).

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Amsterdam	11065	Urogenital	IMPOTENCE	IMPOTENCE	1		Lost to follow-up	
	11066	Body	ABDOMINAL PAIN LOCALIZED	STOMACH PAIN	68	126	Recovered	
			CHILLS	COLD SENSATION IN FINGERTIPS	0		Not recovered	Yes
		Nervous	INSOMNIA	MIDDLE INSOMNIA	57		Not recovered	Yes
		Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	15	79	Recovered	
	11134	Urogenital	EJACULATION ABNORMAL	PREMATURE EJACULATION	31		Not recovered	Yes
	11159	Digestive	NAUSEA	NAUSEA (INTERMITTENT)	16		Lost to follow-up	
	11160	Digestive	CONSTIPATION	CONSTIPATION	6	56	Recovered	
Barbee	21053	Digestive	DRY MOUTH	INCREASED DRY MOUTH	12	56	Recovered	
		Nervous	EMOTIONAL LABILITY	MOOD LABILITY	37	56	Recovered	
			NERVOUSNESS	IRRITABILITY	21	53	Recovered	
		Special Senses	TASTE PERVERSION	METALLIC TASTE	25	56	Recovered	
		Urogenital	URINATION IMPAIRED	URINARY HESITANCY	2	56	Recovered	
Croft	231001	Digestive	DRY MOUTH	DRY MOUTH	9	134	Recovered	
		Nervous	INSOMNIA	INSOMNIA	0	134	Recovered	
		Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	9	134	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Croft	231001	Urogenital	RETENTION URINARY	URINE RETENTION		140	Recovered	
	231080	Body	ABDOMINAL CRAMP	STOMACH CRAMPS	8	51	Recovered	
			HEADACHE	HEADACHES	13	52	Recovered	
		Cardiovascular	VASODILATION	NIGHTLY HOT FLASHES	11		Not recovered	Yes
		Nervous	INSOMNIA	INSOMNIA	0	52	Recovered	
		Urogenital	RETENTION URINARY	URINE RETENTION	22	52	Recovered	
	231119	Body	ABDOMINAL DISTENSION	ABDOMINAL BLOATING	38		Not recovered	Yes
		Digestive	APPETITE DECREASED	DECREASED APPETITE	32	233	Recovered	
			THROAT DRY	DRY THROAT	1		Not recovered	Yes
		Nervous	ANXIETY	ANXIETY	34		Not recovered	Yes
			CHANGE IN DREAMS	VIVID DREAMS	3		Not recovered	Yes
			NERVOUSNESS	IRRITABILITY	14		Not recovered	Yes
		Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	39	233	Recovered	
	231139	Nervous	CHANGE IN DREAMS	VIVID DREAMS	8		Not recovered	Yes
Delgado	41069	Metabolic and Nutritional	PERIPHERAL EDEMA	BILATERAL ANKLE EDEMA	63	126	Recovered	
		Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	BILATERAL ANKLE JOINT PAIN	58	126	Recovered	
				BILATERAL KNEE JOINT PAIN	58	126	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Delgado	41069	Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	JOINT PAIN (BILATERAL WRIST)	58	126	Recovered	
		Nervous	ANXIETY	ANXIETY	1	80	Recovered	
			HYPERTONIA	MUSCLE TENSION	15	147	Recovered	
		Skin	ERYTHEMA	2 REDDENED PATCHES OF SKIN ON LEFT LOWER EXTREMITY	57	72	Recovered	
				3 REDDENED PATCHES OF SKIN RIGHT LOWER EXTREMITY	57	72	Recovered	
	41070	Digestive	DRY MOUTH	DRY MOUTH			Not recovered	Yes
		Special Senses	BLURRED VISION	BLURRED VISION	0	64	Recovered	
DuBoff	311017	Nervous	PARESTHESIA	PARESTHESIA FINGER TIPS	78		Unknown	
			SOMNOLENCE	AM SEDATION	62		Unknown	
Dunner	211039	Nervous	INSOMNIA	WORSE INSOMNIA	1	73	Recovered	
	211040	Nervous	CHANGE IN DREAMS	STRANGE DREAMS	59	78	Recovered	
	211109	Digestive	DYSPEPSIA	INDIGESTION	0		Not recovered	Yes
	211145	Digestive	DRY MOUTH	DRY MOUTH	1	57	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Dunner	211145	Nervous	INSOMNIA	INSOMNIA	1	80	Recovered with sequelae	
			LIBIDO DECREASED	DECREASED LIBIDO	1	72	Recovered	
			SOMNOLENCE	DAYTIME SLEEPINESS	1	59	Recovered	
		Skin	DIAPHORETIC	INCREASED SWEATING	1	57	Recovered	
		Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	9	72	Recovered	
	211146	Body	CHILLS	CHILLS	1	115	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	1	80	Recovered	
		Urogenital	IMPOTENCE	IMPOTENCE	36	67	Recovered	
	211147	Body	HEADACHE	HEADACHE	2		Unknown	
		Nervous	DIZZINESS	LIGHTHEADED	3		Unknown	
Fava	51113	Digestive	DRY MOUTH	DRY MOUTH	4		Not recovered	Yes
	51141	Nervous	NIGHTMARES	NIGHTMARES	7		Recovered	
	51142	Digestive	DRY MOUTH	DRY MOUTH	-126		Not recovered	Yes
Ferguson	241073	Cardiovascular	VASODILATION	HOT FLASHES	21	97	Recovered	
		Nervous	DIZZINESS	LIGHT HEADED	2	97	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Ferguson	241073	Nervous	NERVOUSNESS	INCREASED IRRITABILITY	36	97	Recovered	
	241074	Body	HEADACHE	INCREASED SEVERITY OF HEADACHES	20	78	Recovered	
Gilmer	61081	Digestive	CONSTIPATION	CONSTIPATION	0	12	Recovered	
		Nervous	ATAXIA	ATAXIA	7	75	Recovered	
			DIZZINESS	DIZZINESS	0	12	Recovered	
	61082	Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPS	2		Not recovered	Yes
			CHILLS	CHILLS	2	6	Recovered	
		Digestive	NAUSEA	NAUSEA	1	7	Recovered	
		Nervous	INSOMNIA	INSOMNIA	0		Not recovered	Yes
			MANIC SYMPTOMS	RACING THOUGHTS	3	10	Recovered	
		Skin	DIAPHORETIC	SWEATING	0	6	Recovered	
Halbreich	71077	Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD HANDS	2	65	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	2	65	Recovered	
			DRY MOUTH	DRY MOUTH	2	65	Recovered	
		Nervous	INSOMNIA	INSOMNIA	2	83	Recovered	
			NIGHTMARES	VIOLENT DREAMS	61	65	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Helfing	81003	Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPING	39	69	Recovered	
		Digestive	APPETITE DECREASED	EARLY SATIETY	4	69	Recovered	
			CONSTIPATION	CONSTIPATION	39	69	Recovered	
			DRY MOUTH	DRY MOUTH	37	69	Recovered	
		Nervous	DIZZINESS	DIZZINESS	8	69	Recovered	
			SOMNOLENCE	AM GROGGINESS	29	69	Recovered	
				LETHARGY	42	69	Recovered	
	81004	Nervous	INSOMNIA	INSOMNIA	6		Not recovered	Yes
	81051	Body	ASTHENIA	DECREASED EXERTIONAL ENDURANCE	1	33	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	7	33	Recovered	
			NAUSEA	NAUSEA	21	33	Recovered	
		Nervous	NERVOUSNESS	INCREASED IRRITABILITY	8	33	Recovered	
		Skin	DIAPHORETIC	COLD SWEATS	2	33	Recovered	
			ECZEMA	INCREASED ECZEMA	26	33	Recovered	
			HAIR LOSS	HAIR LOSS	26	33	Recovered	
		Special Senses	BLURRED VISION	BLURRED VISION	7	33	Recovered	
	81075	Cardiovascular	HYPERTENSION	INCREASED BLOOD PRESSURE	166	173	Recovered	
	81103	Cardiovascular	VASODILATION	HOT FLASHES	0	99	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	6	92	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Helfing	81103	Nervous	INSOMNIA	INSOMNIA	0	99	Recovered	
Hoopes	271022	Body	HEADACHE	HEADACHE	69	79	Recovered	
		Digestive	DRY MOUTH	DRY MOUTH	1		Not recovered	Yes
		Special Senses	TINNITUS	TINNITUS	75	79	Recovered	
	271045	Digestive	APPETITE DECREASED	DECREASED APPETITE	2	40	Recovered	
		Nervous	INSOMNIA	INSOMNIA	28	40	Recovered	
Liebowitz	91006	Body	LOCALIZED PAIN	BILATERAL LEG PAIN	47	63	Recovered	
		Cardiovascular	VASODILATION	HEAT FEELINGS (FLUSHING)	45	63	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	48	63	Recovered	
			DRY MOUTH	DRY MOUTH	48	63	Recovered	
	91036	Nervous	ANXIETY	INCREASED ANXIETY	2	4	Recovered	
			DEPRESSIVE SYMPTOMS	INCREASED DEPRESSION	2	4	Recovered	
			HOSTILITY	ANGRY MOOD	2	4	Recovered	
			INSOMNIA	SLEEPING DIFFICULTIES	2	4	Recovered	
	91097	Digestive	APPETITE INCREASED	INCREASED APPETITE	23		Lost to follow-up	
			DRY MOUTH	DRY MOUTH	27		Lost to follow-up	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Liebowitz	91137	Body	HEADACHE	HEADACHE	35	75	Recovered	
		Digestive	DRY MOUTH	DRY MOUTH	35	75	Recovered	
		Nervous	DIZZINESS	DIZZINESS	29		Not recovered	Yes
		Respiratory	RHINITIS	RUNNY NOSE	43	75	Recovered	
		Special Senses	DRY EYES	DRY EYES	31	75	Recovered	
	91138	Body	HEADACHE	HEADACHES	30	51	Recovered	
		Nervous	INSOMNIA	INITIAL INSOMNIA	16		Not recovered	Yes
Londborg	101009	Digestive	DRY MOUTH	DRY MOUTH	20	28	Recovered	
		Nervous	CONCENTRATION IMPAIRED	DECREASED CONCENTRATION	15	28	Recovered	
			SOMNOLENCE	SOMNOLENCE	1	28	Recovered	
	101010	Digestive	DRY MOUTH	DRY MOUTH	1		Unknown	
		Nervous	DIZZINESS	DIZZINESS	5		Unknown	
		Skin	DIAPHORETIC	INCREASED SWEATING	1		Unknown	
	101044	Nervous	INSOMNIA	INSOMNIA	7		Not recovered	Yes
Lydiard	221034	Body	FATIGUE	FATIGUE	-7	42	Recovered	
	221129	Cardiovascular	VASODILATION	HOT FLASHES	1	7	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Lydiard	221129	Nervous	AGITATION	AGITATION	1	7	Recovered	
			INSOMNIA	INSOMNIA	1	9	Recovered	
		Skin	DIAPHORETIC	EXCESSIVE PERSPIRATION	1	7	Recovered	
		Urogenital	IMPOTENCE	IMPOTENCE	1	12	Recovered	
			URINATION IMPAIRED	URINARY HESITANCY	1	9	Recovered	
McGrath	111057	Body	HEADACHE	HEADACHE	0		Lost to follow-up	
		Urogenital	URINATION IMPAIRED	DIFFCULTY URINATING	0		Lost to follow-up	
Moreines	121007	Nervous	NERVOUSNESS	IRRITABILITY	71		Not recovered	Yes
Munjack	131125	Digestive	DRY MOUTH	DRY MOUTH	32		Not recovered	Yes
	131126	Nervous	INSOMNIA	INCREASED INSOMNIA	0		Not recovered	Yes
Nelson	141041	Body	HEADACHE	HEADACHES	0	70	Recovered	
Rapaport	151085	Digestive	DRY MOUTH	DRY MOUTH	0	15	Recovered	
		Special Senses	BLURRED VISION	BLURRED VISION	0	123	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Rapaport	151086	Body	GENERALIZED EDEMA	EDEMA	29	38	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	0	38	Recovered	
			DRY MOUTH	DRY MOUTH	4	38	Recovered	
	151095	Body	GENERALIZED EDEMA	EDEMA	70		Not recovered	Yes
			HEADACHE	HEADACHES	33		Not recovered	Yes
		Nervous	PARESTHESIA	TINGLING (RIGHT SIDE OF FACE)	107		Not recovered	Yes
		Special Senses	TINNITUS	TINITUS	1		Not recovered	Yes
	151099	Body	ABDOMINAL DISTENSION	BLOATING	1	78	Recovered	
	151100	Body	HEADACHE	HEADACHES	7	53	Recovered	
		Nervous	INSOMNIA	INSOMNIA	34		Not recovered	Yes
	151117	Digestive	DRY MOUTH	DRY MOUTH	0		Not recovered	Yes
	151153	Digestive	DRY MOUTH	DRY MOUTH	14	25	Recovered	
		Urogenital	EJACULATION ABNORMAL	DELAYED EJACULATION	3	25	Recovered	
Smith	281025	Digestive	CONSTIPATION	CONSTIPATION	3	5	Recovered	
		Nervous	ANXIETY	ANXIETY	3	5	Recovered	
			DIZZINESS	DIZZY	3	5	Recovered	
			INSOMNIA	INSOMNIA	0	4	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Smith	281026	Digestive	DRY MOUTH	DRY MOUTH	0	59	Recovered	
		Nervous	INSOMNIA	INSOMNIA	5	59	Recovered	
			NERVOUSNESS	IRRITABLE	5	59	Recovered	
	281101	Digestive	DRY MOUTH	DRY MOUTH	1	79	Recovered	
		Nervous	INSOMNIA	INSOMNIA	19	79	Recovered	
	281102	Body	HEADACHE	HEADACHE	67	73	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	6	180	Recovered	
			NAUSEA	NAUSEA	67	73	Recovered	
		Musculo-Skeletal	MYALGIA	MUSCLE ACHES	66	73	Recovered	
		Nervous	DIZZINESS	DIZZY	66	68	Recovered	
	281107	Body	HEADACHE	HEADACHE	0	35	Recovered	
		Digestive	CONSTIPATION	CONSTIPATION	28	36	Recovered	
			DRY MOUTH	DRY MOUTH	0	35	Recovered	
		Nervous	INSOMNIA	INSOMNIA	0	42	Recovered	
		Skin	DIAPHORETIC	SWEATING	2	35	Recovered	
Telew	171015	Digestive	DRY MOUTH	DRY MOUTH	4	72	Recovered	
		Special Senses	EYE PAIN	BURNING EYES	8	100	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Thase	181083	Nervous	INSOMNIA	SLEEP DIFFICULTY	1		Not recovered	Yes
			LIBIDO DECREASED	DIMINISHED LIBIDO	90	165	Recovered	
		Special Senses	TINNITUS	DIMINISHED OCCURRENCE OF TINNITUS FROM BASELINE	107		Not recovered	Yes
				TINNITUS CHANGED TONE-"HIGH FREQUENCY TO LOW RUMBLE"	14		Not recovered	Yes
		Urogenital	DYSURIA	SLIGHT URINARY ITCHING SENSATION	1		Not recovered	Yes
			IMPOTENCE	ERECTILE DIFFICULTY-OBTAINING, MAINTAINING	119	165	Recovered	
			NOCTURIA	URINARY FREQUENCY AT NIGHT	1		Not recovered	Yes
	181105	Urogenital	DISORDER MENSTRUAL NEC	MENSTRUAL CHANGES	9	91	Recovered	
	181106	Skin	DIAPHORETIC	COLD SWEATS	0		Lost to follow-up	
		Special Senses	TASTE PERVERSION	METALLIC TASTE	0		Lost to follow-up	
		Urogenital	DYSURIA	URINARY PRESSURE	2		Lost to follow-up	
			EJACULATION ABNORMAL	SPONTANEOUS EJACULATORY DISCHARGE	9		Lost to follow-up	
	181136	Digestive	DRY MOUTH	DRY MOUTH	26		Not recovered	Yes
		Nervous	INSOMNIA	RESTLESS SLEEP	8	64	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Trivedi	191013	Skin	DIAPHORETIC	INCREASED SWEATING	40		Lost to follow-up	
	191014	Nervous	CHANGE IN DREAMS	VIVID DREAMS	22		Lost to follow-up	
Walsh	171027	Nervous	INSOMNIA	INSOMNIA	28	95	Recovered	
			MANIC SYMPTOMS	RACING THOUGHTS	12	49	Recovered	
	171028	Nervous	DIZZINESS	LIGHT HEADED	17	29	Recovered	
	171061	Digestive	DRY MOUTH	DRY MOUTH	1	48	Recovered	
			NAUSEA	NAUSEA	26	48	Recovered	
		Metabolic and Nutritional	PERIPHERAL EDEMA	FEET SWELLING	27	48	Recovered	
		Nervous	MANIC SYMPTOMS	HYPOMANIA	27	48	Recovered	
	171062	Cardiovascular	VASODILATION	HOT FLASHES	0		Not recovered	Yes
Zajecka	201091	Body	ASTHENIA	TIREDNESS	3		Not recovered	Yes
		Digestive	DRY MOUTH	DRY MOUTH	0		Not recovered	Yes
	201092	Digestive	CONSTIPATION	CONSTIPATION	2		Not recovered	Yes

Note: Onset day and stop day are relative to Baseline.

Table AE18

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Post Study Follow-up of Adverse Events
All Enrolled Patients

Date Produced: January 17, 2001

Inv. Name	Patient Number	Body System	COSTART Term	AE Verbatim	AE Onset Day	Stop Day	AE Outcome	AE Resolved /Chronic
Zajecka	201123	Digestive	CONSTIPATION	CONSTIPATION	14	66	Recovered	
			DRY MOUTH	DRY MOUTH	9	64	Recovered	
		Nervous	DIZZINESS	DIZZINESS	11	62	Recovered	

Note: Onset day and stop day are relative to Baseline.

Table VS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Weight (lb)	Mean	176.6	175.4	175.7	177.5	179.2	180.3	181.1	182.3	182.5
	SD	40.7	40.7	40.9	41.3	41.5	41.7	42.6	40.1	41.2
	n	126	123	116	108	106	100	95	87	79
	Min	104.0	104.0	114.0	109.0	116.0	115.0	111.0	116.0	115.0
	Max	330.0	327.0	329.0	326.0	329.0	327.0	331.0	300.0	294.0
Systolic Blood Pressure (mmHg)	Mean	122.7	122.2	120.9	120.6	121.5	122.2	122.8	123.4	121.8
	SD	14.4	14.3	12.3	13.0	13.2	12.9	13.0	13.3	12.8
	n	128	123	116	108	106	100	96	87	79
	Min	90.0	96.0	94.0	96.0	97.0	100.0	99.0	91.0	90.0
	Max	170.0	180.0	165.0	170.0	168.0	160.0	168.0	160.0	154.0
Diastolic Blood Pressure (mmHg)	Mean	78.6	79.1	79.2	78.9	79.4	80.2	80.4	80.8	80.5
	SD	8.9	8.8	8.3	8.3	7.5	8.1	6.9	8.9	8.2
	n	128	123	116	108	106	100	96	87	79

(CONTINUED)

Table VS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Diastolic Blood Pressure (mmHg)	Min	58.0	58.0	56.0	60.0	62.0	60.0	60.0	59.0	56.0
	Max	100.0	110.0	104.0	98.0	98.0	100.0	98.0	104.0	98.0
Sitting Pulse/Min	Mean	71.4	78.7	79.9	80.1	82.4	80.7	82.4	82.2	82.0
	SD	9.1	10.6	9.6	11.1	11.1	11.4	9.6	10.1	10.6
	n	128	123	116	108	106	100	96	87	79
	Min	48.0	52.0	60.0	60.0	48.0	60.0	60.0	56.0	60.0
	Max	93.0	106.0	108.0	110.0	120.0	112.0	104.0	101.0	108.0
Temperature (F)	Mean	98.1	98.1	98.1	97.9	98.0	98.0	98.0	97.9	98.1
	SD	0.7	0.8	0.7	0.7	0.6	0.6	0.7	0.8	0.6
	n	125	122	115	107	105	99	95	86	79
	Min	94.8	95.1	95.6	96.0	96.2	96.0	95.9	95.5	96.0
	Max	99.5	99.6	99.5	99.2	99.0	99.3	99.7	99.1	99.6
Respiration Rate/Min	Mean	16.7	16.7	16.6	16.5	16.7	16.4	16.6	16.8	16.5

(CONTINUED)

Table VS1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Respiration Rate/Min	SD	2.7	2.5	2.4	2.2	2.2	2.1	2.1	2.5	2.5
	n	127	122	116	108	106	100	96	87	79
	Min	10.0	12.0	12.0	12.0	12.0	11.0	12.0	8.0	12.0
	Max	28.0	24.0	28.0	22.0	22.0	22.0	22.0	24.0	24.0

Table VS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Weight (lb)	Baseline mean	176.5	176.2	177.8	179.6	180.1	180.3	181.7	182.0
	Mean Change	-1.2	-0.6	-0.5	-0.5	0.0	0.8	0.5	0.4
	SD of Change	2.5	3.2	4.3	3.7	3.8	4.2	4.1	4.5
	n	121	114	106	104	98	93	85	77
	Min	-8.0	-11.0	-26.0	-9.0	-9.0	-9.0	-10.0	-9.0
	Max	7.0	10.0	8.0	8.0	10.0	11.0	14.0	12.0
	P-value	0.0000	0.0488	0.2789	0.1887	0.9576	0.0847	0.2537	0.4059
Systolic Blood Pressure (mmHg)	Baseline mean	123.0	123.0	123.0	123.5	123.7	123.3	122.9	122.3
	Mean Change	-0.7	-2.1	-2.4	-2.0	-1.5	-0.6	0.6	-0.4
	SD of Change	11.3	11.0	11.4	13.5	12.5	14.1	12.6	12.5
	n	123	116	108	106	100	96	87	79
	Min	-36.0	-32.0	-40.0	-56.0	-46.0	-52.0	-40.0	-46.0
	Max	25.0	22.0	24.0	34.0	30.0	58.0	23.0	28.0

(CONTINUED)

Table VS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Systolic Blood Pressure (mmHg)	P-value	0.4777	0.0414	0.0311	0.1226	0.2388	0.6964	0.6834	0.7532
Diastolic Blood Pressure (mmHg)	Baseline mean	78.8	79.0	79.1	79.1	79.5	79.3	79.4	79.3
	Mean Change	0.4	0.2	-0.3	0.3	0.6	1.0	1.4	1.2
	SD of Change	7.8	7.7	8.0	7.0	7.2	8.7	8.8	8.6
	n	123	116	108	106	100	96	87	79
	Min	-30.0	-22.0	-20.0	-20.0	-16.0	-20.0	-20.0	-20.0
	Max	21.0	22.0	22.0	16.0	19.0	20.0	25.0	19.0
	P-value	0.5863	0.7911	0.7357	0.6881	0.3866	0.2512	0.1423	0.2109
Sitting Pulse/Min	Baseline mean	71.3	71.4	71.7	71.1	71.1	70.8	71.3	71.0
	Mean Change	7.4	8.5	8.5	11.3	9.6	11.6	11.0	11.0
	SD of Change	10.7	11.4	12.6	12.7	12.2	11.1	12.5	11.9
	n	123	116	108	106	100	96	87	79

(CONTINUED)

Table VS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Sitting Pulse/Min	Min	-20.0	-20.0	-32.0	-44.0	-32.0	-28.0	-28.0	-20.0
	Max	36.0	36.0	42.0	48.0	37.0	40.0	41.0	37.0
	P-value	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000
Temperature (F)	Baseline mean	98.1	98.1	98.1	98.1	98.1	98.1	98.1	98.1
	Mean Change	-0.0	-0.0	-0.2	-0.1	-0.1	-0.1	-0.3	-0.1
	SD of Change	0.7	0.7	0.8	0.6	0.6	0.8	0.9	0.7
	n	121	112	104	102	96	92	84	76
	Min	-1.9	-1.7	-1.9	-1.4	-1.4	-2.5	-2.5	-3.3
	Max	1.6	1.5	1.8	1.5	1.2	1.6	1.3	1.9
	P-value	0.6261	0.9669	0.0164	0.2094	0.1079	0.2376	0.0035	0.2542
Respiration Rate/Min	Baseline mean	16.6	16.6	16.6	16.6	16.6	16.6	16.6	16.6
	Mean Change	0.1	0.0	-0.1	0.1	-0.1	-0.0	0.3	-0.0
	SD of Change	2.5	3.0	2.5	3.1	3.0	3.2	2.9	3.5

(CONTINUED)

Table VS2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Vital Signs and Weight - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 12, 2001

Vital Signs and Weight		Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Respiration Rate/Min	n	121	115	107	105	99	95	86	78
	Min	-8.0	-16.0	-8.0	-12.0	-12.0	-12.0	-12.0	-16.0
	Max	12.0	16.0	10.0	10.0	10.0	10.0	10.0	10.0
	P-value	0.6891	0.9246	0.6946	0.6829	0.6866	0.9496	0.3908	0.9742

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	177.8	182.8
	SD	33.2	50.0
	n	24	22
	Min	115	123
	Max	250	294
Week 9	Mean	178.0	183.0
	SD	33.2	49.3
	n	24	22
	Min	116	123
	Max	248	291
Week 10	Mean	180.1	187.8
	SD	32.9	49.6

(CONTINUED)

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	116	123
	Max	255	291
Week 11	Mean	181.9	194.1
	SD	35.8	50.0
	n	16	15
	Min	116	128
	Max	253	292
Week 12	Mean	189.9	196.9
	SD	29.0	51.9
	n	14	13
	Min	148	129

(CONTINUED)

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	250	290
Week 13	Mean	191.1	204.1
	SD	31.0	55.8
	n	13	10
	Min	148	130
	Max	252	289
Week 14	Mean	186.3	200.8
	SD	33.2	59.0
	n	12	9
	Min	127	129
	Max	250	293
Week 15	Mean	194.7	200.8

(CONTINUED)

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	29.5	58.8
	n	10	9
	Min	148	129
	Max	253	295
Week 16	Mean	190.5	202.8
	SD	29.9	62.8
	n	11	8
	Min	147	128
	Max	254	294
Week 20	Mean	184.9	212.1
	SD	30.1	59.3
	n	9	7

(CONTINUED)

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	148	127
	Max	251	291
Week 24	Mean	190.8	194.6
	SD	46.8	56.2
	n	4	5
	Min	145	129
	Max	253	261
Week 28	Mean		192.0
	SD		55.7
	n		5
	Min		130
	Max		261

(CONTINUED)

Table VS3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Weight by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		198.3
	SD		57.4
	n		3
	Min		158
	Max		264

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	120.8	121.6
	SD	11.7	12.6
	n	24	22
	Min	100	90
	Max	152	140
Week 9	Mean	122.6	127.6
	SD	14.7	14.5
	n	24	22
	Min	104	92
	Max	150	154
Week 10	Mean	124.8	125.6
	SD	11.3	13.2

(CONTINUED)

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	104	96
	Max	142	152
Week 11	Mean	125.3	127.0
	SD	12.7	15.5
	n	16	15
	Min	102	105
	Max	148	150
Week 12	Mean	127.9	130.9
	SD	14.0	10.3
	n	14	13
	Min	110	116

(CONTINUED)

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	156	150
Week 13	Mean	126.5	121.5
	SD	10.3	6.8
	n	13	10
	Min	110	110
	Max	140	134
Week 14	Mean	126.6	123.1
	SD	16.9	9.1
	n	12	9
	Min	100	104
	Max	155	138
Week 15	Mean	123.5	124.8

(CONTINUED)

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	12.5	12.2
	n	10	9
	Min	108	110
	Max	146	148
Week 16	Mean	127.2	119.9
	SD	13.9	9.6
	n	11	8
	Min	106	110
	Max	148	135
Week 20	Mean	134.6	119.7
	SD	22.4	12.8
	n	9	7

(CONTINUED)

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	102	105
	Max	171	134
Week 24	Mean	132.5	117.0
	SD	17.3	9.3
	n	4	5
	Min	110	102
	Max	148	127
Week 28	Mean		117.4
	SD		4.6
	n		5
	Min		110
	Max		121

(CONTINUED)

Table VS4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Systolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		118.0
	SD		7.2
	n		3
	Min		110
	Max		124

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	80.0	80.5
	SD	6.9	9.5
	n	24	22
	Min	70	56
	Max	92	94
Week 9	Mean	81.0	82.6
	SD	7.5	9.2
	n	24	22
	Min	68	68
	Max	96	98
Week 10	Mean	83.2	80.9
	SD	9.3	9.6

(CONTINUED)

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	70	56
	Max	104	98
Week 11	Mean	82.1	82.3
	SD	9.2	9.6
	n	16	15
	Min	68	64
	Max	98	98
Week 12	Mean	80.1	82.8
	SD	9.0	8.4
	n	14	13
	Min	64	64

(CONTINUED)

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	96	94
Week 13	Mean	80.8	79.1
	SD	8.2	8.3
	n	13	10
	Min	64	70
	Max	92	96
Week 14	Mean	84.3	77.1
	SD	8.0	6.8
	n	12	9
	Min	70	66
	Max	96	86
Week 15	Mean	80.4	79.9

(CONTINUED)

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	8.5	5.4
	n	10	9
	Min	70	70
	Max	94	88
Week 16	Mean	80.9	80.8
	SD	5.5	8.1
	n	11	8
	Min	70	70
	Max	87	92
Week 20	Mean	85.8	81.0
	SD	10.0	8.4
	n	9	7

(CONTINUED)

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	70	70
	Max	99	94
Week 24	Mean	88.5	78.8
	SD	18.0	6.9
	n	4	5
	Min	70	72
	Max	110	90
Week 28	Mean		75.6
	SD		5.5
	n		5
	Min		70
	Max		82

(CONTINUED)

Table VS5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Diastolic Blood Pressure (mmHg) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		78.0
	SD		3.5
	n		3
	Min		74
	Max		80

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	84.0	81.3
	SD	10.6	9.2
	n	24	22
	Min	64	64
	Max	105	96
Week 9	Mean	80.0	79.0
	SD	10.1	7.9
	n	24	22
	Min	62	68
	Max	107	96
Week 10	Mean	80.7	80.9
	SD	12.0	10.2

(CONTINUED)

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	56	68
	Max	100	104
Week 11	Mean	80.3	81.6
	SD	10.8	11.4
	n	16	15
	Min	60	62
	Max	96	100
Week 12	Mean	84.1	81.8
	SD	14.2	9.1
	n	14	13
	Min	60	69

(CONTINUED)

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	110	96
Week 13	Mean	83.0	78.4
	SD	13.4	12.3
	n	13	10
	Min	60	54
	Max	100	96
Week 14	Mean	85.5	77.0
	SD	12.6	12.9
	n	12	9
	Min	60	52
	Max	106	100
Week 15	Mean	77.9	81.4

(CONTINUED)

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	9.4	12.1
	n	10	9
	Min	60	59
	Max	94	102
Week 16	Mean	75.3	78.5
	SD	9.6	17.0
	n	11	8
	Min	60	52
	Max	93	104
Week 20	Mean	80.2	73.6
	SD	13.7	10.6
	n	9	7

(CONTINUED)

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	60	55
	Max	102	84
Week 24	Mean	87.3	72.2
	SD	9.1	12.3
	n	4	5
	Min	80	51
	Max	99	80
Week 28	Mean		71.0
	SD		16.4
	n		5
	Min		48
	Max		86

(CONTINUED)

Table VS6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Sitting Pulse/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		74.0
	SD		2.0
	n		3
	Min		72
	Max		76

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	98.1	97.9
	SD	0.6	0.6
	n	24	22
	Min	97	96
	Max	99	99
Week 9	Mean	98.0	98.0
	SD	0.9	0.7
	n	24	22
	Min	95	97
	Max	99	100
Week 10	Mean	97.8	98.2
	SD	0.7	0.6

(CONTINUED)

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	96	97
	Max	99	99
Week 11	Mean	98.0	98.1
	SD	0.9	0.7
	n	16	15
	Min	97	97
	Max	100	99
Week 12	Mean	98.1	98.2
	SD	1.0	0.7
	n	14	13
	Min	96	97

(CONTINUED)

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	100	99
Week 13	Mean	98.0	97.7
	SD	0.6	0.8
	n	13	10
	Min	97	96
	Max	99	99
Week 14	Mean	97.8	97.8
	SD	0.7	0.8
	n	12	9
	Min	97	96
	Max	99	99
Week 15	Mean	97.7	98.1

(CONTINUED)

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	0.8	0.8
	n	10	9
	Min	97	97
	Max	99	99
Week 16	Mean	97.8	98.3
	SD	0.9	0.9
	n	11	8
	Min	97	97
	Max	100	100
Week 20	Mean	97.8	98.3
	SD	0.6	0.9
	n	9	7

(CONTINUED)

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	96	97
	Max	99	100
Week 24	Mean	98.2	97.9
	SD	0.3	0.9
	n	4	5
	Min	98	96
	Max	98	99
Week 28	Mean		98.0
	SD		0.9
	n		5
	Min		97
	Max		99

(CONTINUED)

Table VS7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Temperature (F) by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		98.1
	SD		0.8
	n		3
	Min		97
	Max		99

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 8	Mean	16.5	16.0
	SD	3.0	2.3
	n	24	22
	Min	12	12
	Max	24	24
Week 9	Mean	16.3	15.9
	SD	2.3	2.0
	n	24	22
	Min	12	12
	Max	20	22
Week 10	Mean	16.1	15.8
	SD	2.3	1.7

(CONTINUED)

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 10	n	23	19
	Min	12	12
	Max	20	20
Week 11	Mean	17.5	16.4
	SD	1.9	1.7
	n	16	15
	Min	14	14
	Max	20	20
Week 12	Mean	16.2	16.5
	SD	3.1	1.5
	n	13	13
	Min	12	14

(CONTINUED)

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 12	Max	24	20
Week 13	Mean	16.6	17.2
	SD	2.8	2.5
	n	13	10
	Min	12	16
	Max	20	24
Week 14	Mean	16.8	17.2
	SD	3.2	2.5
	n	12	9
	Min	12	14
	Max	24	22
Week 15	Mean	15.5	18.0

(CONTINUED)

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 15	SD	3.4	2.6
	n	10	9
	Min	10	16
	Max	20	24
Week 16	Mean	16.7	17.1
	SD	2.6	2.0
	n	11	8
	Min	12	15
	Max	20	20
Week 20	Mean	15.8	17.0
	SD	2.9	1.9
	n	9	7

(CONTINUED)

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 20	Min	12	14
	Max	19	20
Week 24	Mean	16.8	15.8
	SD	2.5	1.1
	n	4	5
	Min	14	14
	Max	20	17
Week 28	Mean		15.0
	SD		1.0
	n		5
	Min		14
	Max		16

(CONTINUED)

Table VS8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Respiration Rate/Min by Treatment Group - Summary Statistics by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 12, 2001

Visit		RBX (N=24)	Placebo (N=22)
Week 32	Mean		15.7
	SD		1.5
	n		3
	Min		14
	Max		17

Table VS9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Clinically Significant Changes in Vital Signs
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Treatment	Visit	Wt. (lb)	SBP (mmHg)	DBP (mmHg)	Pulse/ min	Temp. (F)	Resp. rate/ min	Sign. change	Comment
Clayton	31047	27/Female	RBX	Screen	201	114	84	76	98.8	16		
				Day 1	205	110	70	72	98.9	16		
				Week 1	198	120	80	84	98.8	18	No	.
				Week 2	197	110	80	88	98.8	18	No	.
				Week 3	200	114	80	90	98.9	18	No	.
				Week 4	200	110	80	88	98.8	20	No	.
				Week 5	201	110	76	92	98.5	16	No	.
				Week 6	200	110	76	92	98.8	20	No	.
				Week 7	200	110	80	92	98.7	20	No	.
				Week 8	200	114	80	108	98.7	20	Yes	TACHYCARDIA (NOT AN AE)
Helfing	81075	37/Female	RBX	Screen	217	120	78	72	97.7	12		
				Day 1	220	120	78	76	97.5	12		
				Week 1	216	118	80	82	98.2	15	No	.
				Week 2	215	120	82	76	98.8	16	No	.
				Week 3	213	116	82	62	97.7	14	No	.
				Week 4	215	130	80	88	97.1	15	No	.
				Week 5	215	118	82	72	98	14	No	.
				Week 6	212	118	84	82	98.2	16	No	.
				Week 7	212	116	78	80	97.3	14	No	.
				Week 8	211	122	84	84	97.9	14	No	.
				Week 9	213	118	84	84	97.9	14	No	.
				Week 10	208	118	82	84	97.9	12	No	.
				Week 11	208	116	78	78	97.2	14	No	.
				Week 12	208	122	82	82	99.5	15	No	.

Table VS9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Clinically Significant Changes in Vital Signs
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Treatment	Visit	Wt. (lb)	SBP (mmHg)	DBP (mmHg)	Pulse/ min	Temp. (F)	Resp. rate/ min	Sign. change	Comment
Helfing	81075	37/Female	RBX	Week 13	206	140	92	100	98.4	20	No	.
				Week 14	205	116	82	78	97.4	14	No	.
				Week 15	203	118	80	79	97.2	15	No	.
				Week 16	203	120	82	82	97.8	14	No	.
				Week 20	202	138	99	90	98	19	No	.
				Week 32/Final	198	148	110	90	98	20	Yes	INCREASED BLOOD PRESSURE
Hoopes	271045	18/Male	RBX	Screen	120	128	94	66	97.5	18		
				Day 1	122	134	84	80	98.1	16		
				Week 1	117	120	80	84	97.1	16	Yes	WEIGHT LOSS
				Week 2	114	120	80	82	97.5	16	No	.
				Week 3	115	116	90	60	96.2	16	No	.
				Week 4	116	112	90	86	97.7	16	No	.
				Week 8	115	120	90	60	96.9	16	No	.
Londborg	101010	51/Female	RBX	Screen	178	120	60	64	98.2	12		
				Day 1	180	126	77	69	98.8	12		
				Week 1	178	120	79	89	98.6	14	No	.
				Week 2	181	117	77	88	98.8	16	No	.
				Week 3	180	123	79	93	98.8	16	No	.
				Week 4	179	119	85	87	97.4	16	No	.
				Week 5	179	120	82	100	98.8	16	Yes	TACHYCARDIA
				Week 6	180	114	76	89	98.8	16	No	.
				Week 7	180	120	81	98	98.6	16	No	.

Table VS9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Clinically Significant Changes in Vital Signs
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Treatment	Visit	Wt. (lb)	SBP (mmHg)	DBP (mmHg)	Pulse/ min	Temp. (F)	Resp. rate/ min	Sign. change	Comment
Londborg	101010	51/Female	RBX	Week 8	178	154	92	93	98.8	18	No	.
McGrath	111057	48/Male	RBX	Screen	176	122	86	74		24		
				Day 1	178	130	82	72	98.5	12		
				Week 1	178	124	82	64	97.5	24	No	.
				Week 2	184	120	82	88	98.4	28	Yes	PULSE INCREASED BY 24 POINTS (PT JUST HAD COFFEE)
				Week 8								.
Zajecka	201067	31/Male	RBX	Screen	198	122	70	60	97.5	12		
				Day 1	194	118	80	62	98.5	12		
				Week 1	198	138	78	78	98.3	13	Yes	INCREASE IN PULSE, NOT CLINICALLY SIGNIFICANT
				Week 2	192	116	72	68	98	12	No	.
				Week 3	197	114	70	72	98.2	16	No	.
				Week 4	197	124	80	64	97.2	16	No	.
				Week 5	194	110	80	62	97.1	16	No	.
				Week 6	199	110	80	66	97.4	16	No	.
				Week 7	196	104	80	66	98.8	16	No	.
				Week 8	196	114	80	76	97.4	16	No	.
				Week 9	196	104	80	66	97.2	14	No	.
				Week 10	197	124	88	88	97.6	18	No	.
				Week 11	198	138	82	88	98.4	18	No	.
				Week 12	196	138	78	84	97.7	12	No	.

Table VS9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Clinically Significant Changes in Vital Signs
All Enrolled Patients

Date Produced: January 12, 2001

Inv. Name	Patient Number	Age/Sex	Treatment	Visit	Wt. (lb)	SBP (mmHg)	DBP (mmHg)	Pulse/ min	Temp. (F)	Resp. rate/ min	Sign. change	Comment
_												
Zajecka	201067	31/Male	RBX	Week 13	195	118	78	80	97.8	12	No	.
				Week 14	195	104	80	80	97.5	12	No	.
				Week 15	195	118	74	72	97.3	12	No	.
				Week 16	195	122	78	72	98.1	12	No	.
				Week 32/Final	199	132	80	72	97.6	12	No	.

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
ACETAMINOPHEN(APAP)	2	1.6
ACYCLOVIR SYSTEMIC	1	0.8
ADALAT	1	0.8
ADVIL	8	6.3
AFRIN	1	0.8
ALBUTEROL SULFATE	2	1.6
ALEVE	3	2.3
ALLEGRA-D	2	1.6
AMBIEN	5	3.9
AMINO ACID (AS SOLUTION)(POLYPEPTIDES-PARENTERAL)	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
ANTIOXIDANT	1	0.8
ASPIRIN (ACETYLSALICYLIC ACID,ASA)	8	6.3
ATENOLOL	2	1.6
ATROVENT	1	0.8
AZMACORT	1	0.8
BEE POLLEN	1	0.8
BIOTIN	1	0.8
CALAN	1	0.8
CALCIUM	7	5.5
CALCIUM WITH/ MAGNESIUM	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
CALTRATE	1	0.8
CEFTIN	1	0.8
CELEBREX/CELECOXIB	2	1.6
CENTRUM	2	1.6
CHROMIUM PICOLINATE	1	0.8
CITRACAL	1	0.8
CITRUCEL	1	0.8
CLARITIN	6	4.7
CLARITIN D/LORATADINE W/PSEUDOEPHEDRINE SULPHATE	2	1.6
CLIMARA	2	1.6

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
CLOBETASOL PROPIONATE	1	0.8
COZAAR/LOSARTAN POTASSIUM	1	0.8
DARVOCET-N	2	1.6
DEPO-PROVERA CONTRACEPTIVE INJ.	1	0.8
DESOGEN	1	0.8
DETROL (DETRUSITOL)/TOLTERODINE	1	0.8
DIMETAPP	1	0.8
DIUREX	1	0.8
DRIXORAL	1	0.8
DRUG, UNRECOGNIZABLE	2	1.6

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
DURATUSS	1	0.8
ENZYME NOS	1	0.8
ESTRACE	9	7.0
ESTRADERM	1	0.8
ESTRADIOL ORAL	1	0.8
ESTRATEST	1	0.8
ESTROGEN	2	1.6
EVENING PRIMROSE OIL	1	0.8
EX-LAX	1	0.8
EXCEDRIN	4	3.1
EXTRA STRENGTH TYLENOL PM	3	2.3

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
FAMVIR	1	0.8
FLONASE	1	0.8
FOLIC ACID (FOLACIN)	1	0.8
GARLIC	1	0.8
GINKGO BILOBA	1	0.8
GLUCOSAMINE SULPHATE	2	1.6
HOMEOPATHIC MEDICINE	3	2.3
HYDROCHLOROTHIAZIDE (HCTZ)	1	0.8
HYDROCORTISONE (CORTISOL)RECTAL	1	0.8
IBUPROFEN	19	14.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
IMITREX/SUMATRIPTAN	5	3.9
INDAPAMIDE	1	0.8
IRON	2	1.6
K-DUR	1	0.8
LACTOBACILLUS ACIDOPHILUS	1	0.8
LAMISIL	1	0.8
LEVSIN	1	0.8
LIDEX	1	0.8
LIPITOR	2	1.6
LOESTRIN 21	1	0.8
M.V.I.	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
MACROBID	1	0.8
MAXZIDE	1	0.8
MECLIZINE HCL (MECLOZINE HCL)	1	0.8
MEDROXYPROGESTERONE ACETATE	2	1.6
METAMUCIL	1	0.8
METROGEL	1	0.8
MIGRAINE MEDICINE	1	0.8
MINOCYCLINE	1	0.8
MIRCETTE/DESOGESTREL W/ETHINYL ESTRADIOL	1	0.8
MOTRIN TABLETS	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
MULTIVITAMINS	19	14.8
MYLANTA	1	0.8
NAPROSYN	1	0.8
NAPROXEN	1	0.8
NASACORT	1	0.8
NASONEX	1	0.8
NECON/ORTHO-NOVUM	1	0.8
NORPLANT SYSTEM	2	1.6
NORVASC	2	1.6
NUTRITIONAL SUPPLEMENT	1	0.8
ORTHO NOVUM 7/7/7	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
ORTHO TRI CYCLEN	2	1.6
ORTHO-NOVUM	1	0.8
PEPCID AC	2	1.6
PERCOCET	2	1.6
PILOCARPINE HCL	1	0.8
PRAVACHOL	1	0.8
PREMARIN	6	4.7
PREMPRO	2	1.6
PREVACID	2	1.6
PRILOSEC (LOSEC)	1	0.8
PRINIVIL	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
PROGESTERONE	1	0.8
PROPECIA	1	0.8
PROPRANOLOL	1	0.8
PROPULSID	1	0.8
PROTOSTAT	1	0.8
PROVENTIL	1	0.8
PROVERA	4	3.1
PROZAC	1	0.8
REGLAN	1	0.8
RESTORIL	1	0.8
RHINOCORT	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
SEPTRA	1	0.8
SINEMET-10/100	1	0.8
SINUS MEDICATION	1	0.8
SLOW FE	1	0.8
STRESS FORMULA	1	0.8
SUDAFED	2	1.6
SUMATRIPTAN	1	0.8
SYNTHROID	9	7.0
TAGAMET	1	0.8
TEMAZEPAM	2	1.6
TIMOLOL MALEATE	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
TRI-NORINYL	1	0.8
TRIAMTERENE	1	0.8
TRIAMTERENE W/HYDROCHLOROTHIAZIDE (HCTZ)	1	0.8
TRIMOX	1	0.8
TRUSOPT	1	0.8
TUMS	3	2.3
TYLENOL	2	1.6
TYLENOL EXTRA STRENGTH	1	0.8
TYLENOL MAXIMUM STRENGTH SINUS	1	0.8
TYLENOL W/CODEINE NO. 3	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
VANCERIL	1	0.8
VENTOLIN/SALBUTAMOL SULPHATE	1	0.8
VICODIN	3	2.3
VITAMIN A	1	0.8
VITAMIN B COMPLEX	1	0.8
VITAMIN B COMPLEX W/FOLIC ACID	1	0.8
VITAMIN B1 (THIAMINE HCL)	2	1.6
VITAMIN B12 (CYANOCOBALAMIN CRYSTALLINE, HYDROXOCOBALAMIN)	1	0.8
VITAMIN B12 W/VITAMIN B COMPLEX	1	0.8
VITAMIN B6	1	0.8

(CONTINUED)

Table CM1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Pre-treatment
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	N=128	
	n	%
VITAMIN C	6	4.7
VITAMIN E	7	5.5
XALATAN	1	0.8
XENICAL/ORLISTAT	1	0.8
ZANTAC	2	1.6
ZOCOR	3	2.3
ZOVIRAX SYSTEMIC	1	0.8
ZYDONE	1	0.8

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
ACTIFED	1	0.8
ADVIL	32	25.0
ALBUTEROL SULFATE	1	0.8
ALCOHOL (ETOH)	4	3.1
ALEVE	5	3.9
ALKA SELTZER	5	3.9
ALKA SELTZER PLUS COLD TABLETS	1	0.8
ALLEGRA	1	0.8
ALLEGRA-D	3	2.3
ALLERGY MEDICATION	2	1.6
AMBIEN	19	14.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
AMERGE/NARATRIPTAN HCL	1	0.8
AMOXICILLIN	2	1.6
ANACIN	3	2.3
ANTACID MEDICATION	1	0.8
ASPIRIN (ACETYLSALICYLIC ACID,ASA)	24	18.8
ATARAX	1	0.8
AUGMENTIN	5	3.9
AVAPRO/IRBESARTEN	1	0.8
BACTRIM	1	0.8
BACTRIM DS	3	2.3

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
BENADRYL SYSTEMIC	6	4.7
BETHANECHOL CHLORIDE	2	1.6
BIAXIN	2	1.6
BUTALBITAL	1	0.8
CARDIZEM	1	0.8
CELEBREX/CELECOXIB	2	1.6
CEPHALEXIN	4	3.1
CHITOSAN/GLUCOSAMINE	1	0.8
CHLORPHENIRAMINE MALEATE(CHLORPHENAMINE)	1	0.8
CHROMIUM PICOLINATE	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
CIMETIDINE	1	0.8
CIPRO	4	3.1
CIPROFLOXACIN	1	0.8
CLARITIN	4	3.1
CLEAR EYES	1	0.8
CO-Q-10 (COENZYME Q10)	1	0.8
CODEINE	1	0.8
COLACE	1	0.8
COMPAZINE	1	0.8
COMTREX	2	1.6
CONTAC	3	2.3

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
CONTAC-12 HOUR	1	0.8
CORRECTOL	2	1.6
DARVOCET-N	1	0.8
DEMEROL	2	1.6
DEPO-PROVERA CONTRACEPTIVE INJ.	1	0.8
DIAMOX	1	0.8
DICYCLOMINE	1	0.8
DIPHENHYDRAMINE	1	0.8
DIPRIVAN	1	0.8
DOAN'S PILLS	1	0.8
DOCUSATE SODIUM W/CASANTHRANOL	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
DONNATAL	1	0.8
DRUG, UNRECOGNIZABLE	1	0.8
DULCOLAX	1	0.8
DURATUSS	1	0.8
DYAZIDE	2	1.6
ECHINACEA(PURPLE CONEFLOWER)	1	0.8
ETODOLAC	1	0.8
EX-LAX	1	0.8
EXCEDRIN	17	13.3
EXCEDRIN EXTRA STRENGTH	1	0.8
EXCEDRIN PM	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
EXTRA STRENGTH TYLENOL PM	2	1.6
FELDENE	1	0.8
FENTANYL	1	0.8
FIBER	1	0.8
FIBERALL	1	0.8
FIBERCON	4	3.1
FIORICET	1	0.8
FLEXERIL	1	0.8
FLONASE	2	1.6
FLU(INFLUENZA) VACCINE	3	2.3
FOOD SUPPLEMENTS	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
GABAPENTIN	1	0.8
GAVISCON	1	0.8
GLUCOSAMINE SULPHATE	1	0.8
GLUTATHIONE	1	0.8
GOODY'S HEADACHE POWDERS	5	3.9
GUAIFENESIN	1	0.8
HALL'S MENTHO-LYPTUS COUGH TABLETS	1	0.8
HERBAL MEDICINE	1	0.8
HOMEOPATHIC MEDICINE	3	2.3
HYDROCODONE	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
HYDROCORTISONE (CORTISOL)TOPICAL	1	0.8
IBUPROFEN	24	18.8
IMIPRAMINE HCL	1	0.8
IMODIUM	2	1.6
IRON	1	0.8
KEFLEX	4	3.1
KLONOPIN	2	1.6
L-LYSINE	1	0.8
LACTOBACILLUS ACIDOPHILUS	1	0.8
LAMISIL	1	0.8
LEVAQUIN	2	1.6

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
LORTAB	1	0.8
LOTENSIN	1	0.8
MAALOX PLUS	2	1.6
MACROBID	1	0.8
MARCAINE W/EPINEPHRINE	1	0.8
MARCAINE W/XYLOCAINE (LIDOCAINE)	1	0.8
MAXZIDE	1	0.8
MEDROL TABLETS	1	0.8
METAMUCIL	3	2.3
METROGEL VAGINAL	1	0.8
MICONAZOLE SYSTEMIC	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
MIDOL	1	0.8
MIDRIN	2	1.6
MOTRIN TABLETS	8	6.3
MULTIVITAMINS	2	1.6
MYLANTA	1	0.8
NAPROSYN	1	0.8
NAPROXEN	2	1.6
NAPROXEN SODIUM	1	0.8
NASACORT	1	0.8
NECON/ORTHO-NOVUM	1	0.8
NUTRITIONAL SUPPLEMENT	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
NYQUIL LIQUICAPS	4	3.1
OCUHIST	1	0.8
ORTHO-CYCLEN	1	0.8
PENICILLIN VK	3	2.3
PEPCID AC	2	1.6
PEPTO BISMOL	5	3.9
PERCOCET	2	1.6
PHILLIPS MILK OF MAGNESIA	2	1.6
PILOCARPINE HCL	1	0.8
PRAVACHOL	1	0.8
PREDNISONE (DELTACORTISONE)	2	1.6

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
PREMSYN PMS	1	0.8
PREPARATION H	1	0.8
PRILOSEC (LOSEC)	1	0.8
PROPOXYPHENE NAPSYLATE	1	0.8
PROPULSID	1	0.8
PROVENTIL	1	0.8
PROZAC	2	1.6
PSEUDOEPHEDRINE HCL	2	1.6
PYRIDIUM	1	0.8
RELAFEN	1	0.8
RESTORIL	6	4.7

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
ROBAXIN	1	0.8
ROBITUSSIN	1	0.8
ROLAIDS	1	0.8
RYNATAN	1	0.8
SELENIUM W/VITAMIN E	1	0.8
SEPTRA	1	0.8
SEPTRA DS	1	0.8
SINUS MEDICATION	1	0.8
SKELAXIN	1	0.8
SODIUM CHLORIDE (NORMAL SALINE,ISOTONIC,0.9%,NACL)	2	1.6

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
SODIUM CHLORIDE NASAL	1	0.8
SOMA	1	0.8
STEROID MEDICATION	1	0.8
SUDAFED	3	2.3
SUDAFED SINUS MAXIMUM STRENGTH	1	0.8
SULFAMETHOXAZOLE	1	0.8
SULFONAMIDE - SYSTEMIC	1	0.8
SULINDAC	1	0.8
TAGAMET	2	1.6
TAVIST	2	1.6
TAVIST-D	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
TEMAZEPAM	8	6.3
TETANUS TOXOID	1	0.8
THERAFLU FLU & COLD MEDICINE	3	2.3
TINACTIN	1	0.8
TITRALAC	1	0.8
TRIAMTERENE	1	0.8
TUMS	7	5.5
TUSSIN	1	0.8
TYLENOL	28	21.9
TYLENOL ALLERGY SINUS NIGHT TIME, MAXIMUM STRENGTH	4	3.1

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
TYLENOL COLD MEDICATION	2	1.6
TYLENOL EXTRA STRENGTH	6	4.7
TYLENOL MAXIMUM STRENGTH SINUS	1	0.8
TYLENOL W/CODEINE NO. 3	1	0.8
VALIUM	1	0.8
VALTREX	1	0.8
VANCENASE NASAL INHALER	1	0.8
VENLAFAXINE	1	0.8
VERSED	2	1.6
VIAGRA	1	0.8
VICKS DAYQUIL	2	1.6

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
VICODIN	4	3.1
VIOXX/ROFECOXIB	2	1.6
VISTARIL	1	0.8
VITAMIN B1 (THIAMINE HCL)	1	0.8
VITAMIN C	2	1.6
VIVARIN	1	0.8
VOLTAREN	1	0.8
WELLBUTRIN	1	0.8
XANAX TABLETS	1	0.8
ZANTAC	2	1.6
ZESTORETIC	1	0.8

(CONTINUED)

Table CM2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=128)	
	n	%
ZITHROMAX	3	2.3
ZOCOR	1	0.8
ZOLOFT	1	0.8
ZOLPIDEM TARTRATE	2	1.6
ZYRTEC	1	0.8

Table CM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=24)		Placebo (N=22)	
	n	%	n	%
ADVIL	1	4.2	8	36.4
ALEVE	1	4.2	1	4.5
ALKA SELTZER PLUS COLD TABLETS	.	.	2	9.1
AMOXICILLIN	1	4.2	.	.
AMPICILLIN	1	4.2	.	.
ATENOLOL	.	.	1	4.5
AUGMENTIN	.	.	1	4.5
BENADRYL SYSTEMIC	1	4.2	.	.
BUTALBITAL	.	.	1	4.5
CALCIUM	.	.	1	4.5
CEPHALEXIN	.	.	1	4.5

(CONTINUED)

Table CM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=24)		Placebo (N=22)	
	n	%	n	%
COTYLENOL	1	4.2	.	.
CRANBERRY	.	.	1	4.5
CYCLOBENZAPRINE	.	.	1	4.5
DICLOXACILLIN	.	.	1	4.5
DIPHENHYDRAMINE	.	.	1	4.5
DRAMAMINE II/MECLIZINE W/LACTOSE	.	.	1	4.5
EXCEDRIN PM	.	.	1	4.5
FLONASE	.	.	1	4.5
GUAIFENESIN	.	.	1	4.5
HOMEOPATHIC MEDICINE	2	8.3	.	.
HYDROCODONE	.	.	1	4.5

(CONTINUED)

Table CM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=24)		Placebo (N=22)	
	n	%	n	%
IBUPROFEN	6	25.0	4	18.2
IMITREX/SUMATRIPTAN	.	.	1	4.5
LIDOCAINE HCL LOCAL INJECTABLE ANESTHETIC (LIGNOCAINE)	.	.	1	4.5
MAGNESIUM	.	.	1	4.5
MELATONIN	.	.	1	4.5
MONISTAT 7	.	.	1	4.5
NAPROSYN	1	4.2	.	.
NAPROXEN	.	.	1	4.5
NAPROXEN SODIUM	.	.	1	4.5
NUTRITIONAL SUPPLEMENT	1	4.2	.	.

(CONTINUED)

Table CM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=24)		Placebo (N=22)	
	n	%	n	%
NYQUIL LIQUICAPS	.	.	2	9.1
ORUVAIL	.	.	1	4.5
PROPOXYPHENE NAPSYLATE W/ACETAMINOPHEN	1	4.2	.	.
PROPULSID	1	4.2	.	.
RESTORIL	3	12.5	.	.
ROLAIDS	1	4.2	.	.
SUDAFED	.	.	4	18.2
TAGAMET	.	.	1	4.5
THERAFLU FLU & COLD MEDICINE	1	4.2	.	.
TRIAMINIC	1	4.2	.	.

(CONTINUED)

Table CM3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication: Summary by Therapeutic Class, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Therapeutic Class	RBX (N=24)		Placebo (N=22)	
	n	%	n	%
TUMS	1	4.2	.	.
TYLENOL	1	4.2	4	18.2
TYLENOL EXTRA STRENGTH	4	16.7	.	.
TYLENOL MAXIMUM STRENGTH SINUS	1	4.2	.	.
TYLENOL W/CODEINE NO. 3	1	4.2	.	.
VEETIDS	1	4.2	.	.
VICODIN	1	4.2	1	4.5
VIOXX/ROFECOXIB	1	4.2	.	.
VITAMIN C	1	4.2	.	.
ZINC	.	.	1	4.5

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Hematocrit (%)	Mean	40.9	40.5	40.8
	SD	3.6	3.9	3.6
	n	128	97	113
	Median	40	40	40
	Min	28.0	29.1	30.0
	Max	50.0	49.2	50.3
Hemoglobin (G/DL)	Mean	13.8	13.7	13.8
	SD	1.3	1.3	1.3
	n	128	97	113
	Median	13	13	13
	Min	8.9	9.1	9.7
	Max	16.9	16.4	17.3

(CONTINUED)

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Red Cell Count (M/UL)	Mean	4.5	4.4	4.5
	SD	0.4	0.4	0.4
	n	128	97	113
	Median	4	4	4
	Min	3.6	3.4	3.7
	Max	5.5	5.5	5.6
MCV (FL)	Mean	91.5	91.3	91.5
	SD	4.6	4.8	4.7
	n	128	97	113
	Median	92	92	92
	Min	74.0	73.0	74.0
	Max	103.0	101.0	102.0

(CONTINUED)

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
White Cell Count (K/UL)	Mean	6.5	6.2	6.5
	SD	1.9	1.6	1.8
	n	128	97	113
	Median	6	6	6
	Min	2.7	3.3	3.3
	Max	14.3	10.5	13.1
Total Neutrophils (%)	Mean	61.2	58.6	59.6
	SD	8.8	8.9	9.6
	n	128	97	113
	Median	62	60	60
	Min	33.0	29.9	34.2
	Max	91.0	80.3	85.0

(CONTINUED)

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Lymphocytes (%)	Mean	29.6	31.0	31.0
	SD	8.1	7.5	8.3
	n	128	97	113
	Median	28	30	30
	Min	7.0	16.7	8.0
	Max	58.0	53.2	52.7
Monocytes (%)	Mean	6.3	7.0	6.3
	SD	2.2	2.2	2.3
	n	128	97	113
	Median	6	6	5
	Min	0.3	1.9	1.0
	Max	11.8	13.5	14.1

(CONTINUED)

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Eosinophils (%)	Mean	2.4	3.0	2.7
	SD	1.7	2.1	1.8
	n	128	97	113
	Median	2	2	2
	Min	0.0	0.2	0.0
	Max	12.9	10.5	9.6
Basophils (%)	Mean	0.4	0.5	0.4
	SD	0.3	0.4	0.3
	n	128	97	113
	Median	0	0	0
	Min	0.0	0.0	0.0
	Max	1.7	2.3	1.6

(CONTINUED)

Table LAB1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Visit, Open Phase

All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Platelet Counts (CMM)	Mean	279781.3	285783.5	290362.8
	SD	66851.3	67940.0	65194.4
	n	128	97	113
	Median	269000	279000	284000
	Min	136000.0	160000.0	165000.0
	Max	484000.0	443000.0	515000.0

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Hematocrit (%)	Mean at screen	41.0	40.8
	Mean change	-0.5	0.0
	SD of change	2.1	2.4
	n	97	113
	Median change	0	0
	Min	-4.9	-5.1
	Max	3.5	7.1
	P-value	0.0179	0.9052
Hemoglobin (G/DL)	Mean at screen	13.8	13.7
	Mean change	-0.1	0.0
	SD of change	0.7	0.8
	n	97	113

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Hemoglobin (G/DL)	Median change	0	0
	Min	-1.6	-2.4
	Max	1.5	2.1
	P-value	0.1349	0.6886
Red Cell Count (M/UL)	Mean at screen	4.5	4.5
	Mean change	-0.1	0.0
	SD of change	0.2	0.3
	n	97	113
	Median change	0	0
	Min	-0.6	-0.6
	Max	0.6	1.0
	P-value	0.0249	0.8886

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
MCV (FL)	Mean at screen	91.5	91.5
	Mean change	-0.2	0.0
	SD of change	1.8	2.0
	n	97	113
	Median change	0	0
	Min	-5.0	-7.0
	Max	4.0	6.0
	P-value	0.4096	0.9629
White Cell Count (K/UL)	Mean at screen	6.5	6.6
	Mean change	-0.3	-0.0
	SD of change	1.3	1.5
	n	97	113

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
White Cell Count (K/UL)	Median change	0	0
	Min	-5.3	-6.6
	Max	2.5	3.7
	P-value	0.0254	0.8898
Total Neutrophils (%)	Mean at screen	61.4	61.1
	Mean change	-2.8	-1.5
	SD of change	8.7	8.8
	n	97	113
	Median change	-2	-1
	Min	-29.3	-31.5
	Max	18.6	20.2
	P-value	0.0017	0.0706

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Lymphocytes (%)	Mean at screen	29.7	29.7
	Mean change	1.2	1.3
	SD of change	7.4	7.9
	n	97	113
	Median change	1	1
	Min	-20.5	-20.4
	Max	18.6	27.9
	P-value	0.1045	0.0936
Monocytes (%)	Mean at screen	6.2	6.3
	Mean change	0.8	-0.1
	SD of change	1.9	2.2
	n	97	113

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Monocytes (%)	Median change	0	0
	Min	-3.4	-7.2
	Max	5.9	7.4
	P-value	0.0001	0.7318
Eosinophils (%)	Mean at screen	2.2	2.4
	Mean change	0.8	0.3
	SD of change	1.9	1.5
	n	97	113
	Median change	0	0
	Min	-2.3	-7.2
	Max	8.9	4.1
	P-value	0.0001	0.0211

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Basophils (%)	Mean at screen	0.4	0.5
	Mean change	0.1	-0.0
	SD of change	0.5	0.4
	n	97	113
	Median change	0	0
	Min	-1.0	-1.1
	Max	2.2	1.1
	P-value	0.2554	0.7143
Platelet Counts (CMM)	Mean at screen	281082.5	282300.9
	Mean change	4701.0	8061.9
	SD of change	38112.8	37986.2
	n	97	113

(CONTINUED)

Table LAB2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Platelet Counts (CMM)	Median change	5000	9000
	Min	-88000.0	-94000.0
	Max	171000.0	181000.0
	P-value	0.2274	0.0260

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Hematocrit (%)

Screen	Week 8/Final Visit	n	%
Low	Low	4	57.1
	Normal	3	42.9
	Total Reported	7	100.0
Normal	Low	5	4.8
	Normal	98	93.3
	High	2	1.9
	Total Reported	105	100.0
	Not Reported	15	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Hemoglobin (G/DL)

Screen	Week 8/Final Visit	n	%
Low	Low	7	53.8
	Normal	6	46.2
	Total Reported	13	100.0
Normal	Low	2	2.0
	Normal	95	96.0
	High	2	2.0
	Total Reported	99	100.0
	Not Reported	15	
High	High	1	100.0
	Total Reported	1	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Red Cell Count (M/UL)

Screen	Week 8/Final Visit	n	%
Low	Low	4	50.0
	Normal	4	50.0
	Total Reported	8	100.0
	Not Reported	1	
Normal	Low	4	3.8
	Normal	100	96.2
	Total Reported	104	100.0
	Not Reported	14	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: MCV (FL)

Screen	Week 8/Final Visit	n	%
Low	Low	3	100.0
	Total Reported	3	100.0
Normal	Normal	108	100.0
	Total Reported	108	100.0
	Not Reported	15	
High	Normal	1	50.0
	High	1	50.0
	Total Reported	2	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: White Cell Count (K/UL)

Screen	Week 8/Final Visit	n	%
Low	Low	2	50.0
	Normal	2	50.0
	Total Reported	4	100.0
Normal	Low	2	1.9
	Normal	104	97.2
	High	1	0.9
	Total Reported	107	100.0
	Not Reported	14	
High	Normal	2	100.0
	Total Reported	2	100.0
	Not Reported	1	

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Total Neutrophils (%)

Screen	Week 8/Final Visit	n	%
Low	Normal	4	100.0
	Total Reported	4	100.0
Normal	Low	3	2.9
	Normal	98	96.1
	High	1	1.0
	Total Reported	102	100.0
	Not Reported	14	
High	Normal	5	71.4
	High	2	28.6
	Total Reported	7	100.0
	Not Reported	1	

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Lymphocytes (%)

Screen	Week 8/Final Visit	n	%
Low	Low	1	20.0
	Normal	4	80.0
	Total Reported	5	100.0
	Not Reported	1	
Normal	Low	3	2.9
	Normal	96	92.3
	High	5	4.8
	Total Reported	104	100.0
	Not Reported	14	
High	Normal	4	100.0
	Total Reported	4	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Monocytes (%)

Screen	Week 8/Final Visit	n	%
Normal	Normal	112	99.1
	High	1	0.9
	Total Reported	113	100.0
	Not Reported	15	

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Eosinophils (%)

Screen	Week 8/Final Visit	n	%
Normal	Normal	108	98.2
	High	2	1.8
	Total Reported	110	100.0
	Not Reported	15	
High	Normal	1	33.3
	High	2	66.7
	Total Reported	3	100.0

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Basophils (%)

Screen	Week 8/Final Visit	n	%
Normal	Normal	113	100.0
	Total Reported	113	100.0
	Not Reported	15	

Table LAB3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Platelet Counts (CMM)

Screen	Week 8/Final Visit	n	%
Normal	Normal	101	94.4
	High	6	5.6
	Total Reported	107	100.0
	Not Reported	15	
High	Normal	2	33.3
	High	4	66.7
	Total Reported	6	100.0

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Hematocrit (%)	Mean	41.8	40.9	42.3	40.0
	SD	3.7	2.8	3.7	2.8
	n	24	22	21	21
	Median	40	40	41	39
	Min	35.8	35.6	36.0	34.9
	Max	49.3	46.8	50.7	46.1
Hemoglobin (G/DL)	Mean	14.2	13.8	14.4	13.6
	SD	1.3	1.0	1.3	1.1
	n	24	22	21	21
	Median	13	13	14	13
	Min	12.1	12.0	12.1	11.7
	Max	16.6	16.1	17.2	15.6

(CONTINUED)

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Red Cell Count (M/UL)	Mean	4.6	4.4	4.6	4.4
	SD	0.5	0.4	0.5	0.3
	n	24	22	21	21
	Median	4	4	4	4
	Min	3.9	3.7	4.0	3.8
	Max	5.6	5.2	5.7	5.1
MCV (FL)	Mean	91.9	93.1	91.5	92.0
	SD	3.7	4.2	3.7	3.7
	n	24	22	21	21
	Median	92	93	93	92
	Min	84.0	80.0	85.0	82.0
	Max	98.0	101.0	99.0	97.0

(CONTINUED)

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
White Cell Count (K/UL)	Mean	7.3	6.4	7.0	6.8
	SD	2.1	1.6	2.4	2.1
	n	24	22	21	21
	Median	7	6	5	6
	Min	3.8	3.8	3.9	3.7
	Max	13.1	9.2	11.9	11.4
Total Neutrophils (%)	Mean	61.2	57.7	60.7	58.2
	SD	9.1	10.6	8.0	10.8
	n	24	22	21	21
	Median	61	58	60	58
	Min	46.3	34.2	44.4	38.1
	Max	78.9	74.0	80.0	76.3

(CONTINUED)

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Lymphocytes (%)	Mean	29.5	32.9	30.5	31.8
	SD	7.9	9.0	7.4	8.6
	n	24	22	21	21
	Median	29	30	31	30
	Min	13.7	19.1	12.0	18.5
	Max	43.1	52.7	49.0	50.6
Monocytes (%)	Mean	6.1	6.4	5.4	6.5
	SD	2.1	2.7	2.4	2.6
	n	24	22	21	21
	Median	5	6	5	6
	Min	2.5	1.6	0.0	0.0
	Max	10.4	10.8	9.3	11.5

(CONTINUED)

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Eosinophils (%)	Mean	2.7	2.5	2.9	3.1
	SD	1.6	1.4	2.6	3.8
	n	24	22	21	21
	Median	2	2	2	2
	Min	0.5	0.6	0.3	0.4
	Max	8.2	6.3	13.1	18.8
Basophils (%)	Mean	0.5	0.5	0.4	0.4
	SD	0.3	0.3	0.3	0.3
	n	24	22	21	21
	Median	0	0	0	0
	Min	0.1	0.0	0.0	0.0
	Max	1.2	1.3	1.0	1.2

(CONTINUED)

Table LAB4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Hematology Assays: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Platelet Counts (CMM)	Mean	278416.7	286409.1	283333.3	283952.4
	SD	65372.5	49054.5	65386.8	42981.9
	n	24	22	21	21
	Median	267000	285500	258000	295000
	Min	189000.0	165000.0	205000.0	180000.0
	Max	408000.0	387000.0	427000.0	338000.0

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Alkaline Phosphase (U/L)	Mean	74.0	76.6	73.7
	SD	23.0	25.2	21.3
	n	128	97	112
	Median	69	74	72
	Min	35.0	37.0	36.0
	Max	195.0	184.0	188.0
Bilirubin, Total (MG/DL)	Mean	0.5	0.5	0.5
	SD	0.2	0.3	0.3
	n	128	97	112
	Median	0	0	0
	Min	0.1	0.1	0.2
	Max	1.4	2.2	3.1

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
ASAT (SGOT) (U/L)	Mean	20.0	20.2	20.7
	SD	8.0	7.5	13.2
	n	128	97	112
	Median	18	18	18
	Min	11.0	10.0	11.0
	Max	62.0	64.0	135.0
ALAT (SGPT) (U/L)	Mean	21.5	21.4	21.6
	SD	15.3	12.9	14.9
	n	128	97	112
	Median	18	18	17
	Min	5.0	6.0	7.0
	Max	122.0	93.0	92.0

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Uric Acid (MG/DL)	Mean	4.2	4.3	4.3
	SD	1.3	1.3	1.4
	n	128	97	112
	Median	4	4	4
	Min	0.8	2.0	0.6
	Max	9.2	7.2	7.6
Creatinine (MG/DL)	Mean	0.8	0.8	0.8
	SD	0.2	0.2	0.2
	n	128	97	112
	Median	0	0	0
	Min	0.4	0.4	0.4
	Max	1.4	1.3	1.4

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Glucose (MG/DL)	Mean	93.7	95.0	94.0
	SD	16.3	19.4	18.4
	n	128	97	112
	Median	92	92	92
	Min	60.0	63.0	59.0
	Max	170.0	194.0	173.0
Chloride (MEQ/L)	Mean	103.6	103.9	103.7
	SD	2.3	2.5	2.5
	n	128	97	112
	Median	104	104	104
	Min	98.0	98.0	97.0
	Max	109.0	113.0	109.0

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Urea Nitrogen (MG/DL)	Mean	13.8	14.6	13.9
	SD	3.7	4.0	3.9
	n	128	97	112
	Median	14	14	14
	Min	5.0	7.0	6.0
	Max	26.0	29.0	28.0
Sodium (MEQ/L)	Mean	140.1	140.5	140.1
	SD	2.4	2.6	2.2
	n	128	97	112
	Median	140	140	140
	Min	134.0	134.0	134.0
	Max	149.0	152.0	147.0

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Potassium (MEQ/L)	Mean	4.3	4.4	4.3
	SD	0.3	0.4	0.4
	n	128	97	112
	Median	4	4	4
	Min	3.6	3.2	3.2
	Max	5.3	5.8	5.4
TSH (UIU/ML)	Mean	2.0		2.2
	SD	1.4		
	n	128		1
	Median	1		2
	Min	0.1		2.2
	Max	8.4		2.2

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
Reticulocyte Count (%)	Mean	1.9	1.8	1.8
	SD	0.7	0.8	0.7
	n	125	96	111
	Median	1	1	1
	Min	0.8	0.6	0.5
	Max	4.2	5.9	4.1
T-4 (Thyroxine) (MCG/DL)	Mean	7.5		6.0
	SD	1.6		
	n	128		1
	Median	7		6
	Min	5.0		6.0
	Max	12.2		6.0

(CONTINUED)

Table LAB5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen	Week 4	Week 8/ Final
CO2 Content (MEQ/L)	Mean	26.2	27.5	26.1
	SD	3.0	2.9	2.9
	n	128	97	112
	Median	26	28	26
	Min	17.0	18.0	19.0
	Max	33.0	34.0	34.0

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Alkaline Phosphase (U/L)	Mean at screen	75.6	75.0
	Mean change	1.0	-1.3
	SD of change	9.7	8.8
	n	97	112
	Median change	1	0
	Min	-22.0	-36.0
	Max	32.0	24.0
	P-value	0.3038	0.1095
Bilirubin, Total (MG/DL)	Mean at screen	0.5	0.5
	Mean change	0.0	0.0
	SD of change	0.2	0.3
	n	97	112

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Bilirubin, Total (MG/DL)	Median change	0	0
	Min	-0.4	-0.6
	Max	0.8	2.4
	P-value	0.5130	0.2472
ASAT (SGOT) (U/L)	Mean at screen	19.3	19.9
	Mean change	0.8	0.8
	SD of change	6.2	10.7
	n	97	112
	Median change	1	0
	Min	-22.0	-28.0
	Max	41.0	92.0
	P-value	0.1966	0.4550

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
ALAT (SGPT) (U/L)	Mean at screen	20.6	21.3
	Mean change	0.8	0.3
	SD of change	7.3	10.4
	n	97	112
	Median change	1	0
	Min	-29.0	-57.0
	Max	17.0	42.0
	P-value	0.3069	0.7438
Uric Acid (MG/DL)	Mean at screen	4.2	4.2
	Mean change	0.1	0.2
	SD of change	0.8	0.8
	n	97	112

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Uric Acid (MG/DL)	Median change	0	0
	Min	-2.2	-1.7
	Max	2.1	3.0
	P-value	0.1137	0.0197
Creatinine (MG/DL)	Mean at screen	0.8	0.8
	Mean change	0.0	0.0
	SD of change	0.1	0.2
	n	97	112
	Median change	0	0
	Min	-0.4	-0.4
	Max	0.3	0.4
	P-value	0.8219	0.1099

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Glucose (MG/DL)	Mean at screen	92.9	93.6
	Mean change	2.1	0.4
	SD of change	22.7	18.3
	n	97	112
	Median change	0	2
	Min	-97.0	-90.0
	Max	103.0	44.0
	P-value	0.3657	0.8083
Chloride (MEQ/L)	Mean at screen	103.7	103.6
	Mean change	0.2	0.0
	SD of change	2.9	2.5
	n	97	112

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Chloride (MEQ/L)	Median change	0	0
	Min	-7.0	-6.0
	Max	6.0	5.0
	P-value	0.4861	0.8484
Urea Nitrogen (MG/DL)	Mean at screen	14.0	13.7
	Mean change	0.6	0.2
	SD of change	3.9	3.5
	n	97	112
	Median change	1	0
	Min	-10.0	-10.0
	Max	16.0	10.0
	P-value	0.1519	0.4899

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Sodium (MEQ/L)	Mean at screen	140.1	140.1
	Mean change	0.4	0.0
	SD of change	2.9	2.9
	n	97	112
	Median change	1	0
	Min	-9.0	-7.0
	Max	7.0	11.0
	P-value	0.1774	0.8980
Potassium (MEQ/L)	Mean at screen	4.4	4.3
	Mean change	-0.0	-0.0
	SD of change	0.4	0.4
	n	97	112

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Potassium (MEQ/L)	Median change	0	0
	Min	-0.9	-0.9
	Max	0.8	1.0
	P-value	0.7099	0.2611
TSH (UIU/ML)	Mean at screen		2.0
	Mean change		0.2
	SD of change		
	n		1
	Median change		0
	Min		0.2
	Max		0.2
	P-value		

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
Reticulocyte Count (%)	Mean at screen	1.9	1.9
	Mean change	-0.1	-0.1
	SD of change	0.6	0.6
	n	93	108
	Median change	0	0
	Min	-1.3	-2.0
	Max	3.3	1.1
	P-value	0.0771	0.0062
T-4 (Thyroxine) (MCG/DL)	Mean at screen		6.5
	Mean change		-0.5
	SD of change		
	n		1

(CONTINUED)

Table LAB6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary of Mean Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 4	Week 8/ Final
T-4 (Thyroxine) (MCG/DL)	Median change		0
	Min		-0.5
	Max		-0.5
	P-value		
CO2 Content (MEQ/L)	Mean at screen	26.4	26.2
	Mean change	1.1	-0.1
	SD of change	3.5	3.4
	n	97	112
	Median change	1	0
	Min	-8.0	-8.0
	Max	8.0	10.0
	P-value	0.0039	0.8003

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Alkaline Phosphase (U/L)

Screen	Week 8/Final Visit	n	%
Normal	Normal	107	99.1
	Not Done	1	0.9
	Total Reported	108	100.0
	Not Reported	15	
High	Normal	3	60.0
	High	2	40.0
	Total Reported	5	100.0

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Bilirubin, Total (MG/DL)

Screen	Week 8/Final Visit	n	%
Normal	Normal	111	98.2
	High	1	0.9
	Not Done	1	0.9
	Total Reported	113	100.0
	Not Reported	14	
High	Not Reported	1	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: ASAT (SGOT) (U/L)

Screen	Week 8/Final Visit	n	%
Normal	Normal	107	98.2
	High	1	0.9
	Not Done	1	0.9
	Total Reported	109	100.0
	Not Reported	14	
High	Normal	2	50.0
	High	2	50.0
	Total Reported	4	100.0
	Not Reported	1	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: ALAT (SGPT) (U/L)

Screen	Week 8/Final Visit	n	%
Normal	Normal	105	98.1
	High	1	0.9
	Not Done	1	0.9
	Total Reported	107	100.0
	Not Reported	14	
High	Normal	1	16.7
	High	5	83.3
	Total Reported	6	100.0
	Not Reported	1	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Uric Acid (MG/DL)

Screen	Week 8/Final Visit	n	%
Low	Low	4	33.3
	Normal	8	66.7
	Total Reported	12	100.0
	Not Reported	3	
Normal	Low	4	4.0
	Normal	95	95.0
	Not Done	1	1.0
	Total Reported	100	100.0
	Not Reported	12	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Creatinine (MG/DL)

Screen	Week 8/Final Visit	n	%
Low	Normal	1	100.0
	Total Reported	1	100.0
Normal	Low	2	1.8
	Normal	109	97.3
	Not Done	1	0.9
	Total Reported	112	100.0
	Not Reported	15	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Glucose (MG/DL)

Screen	Week 8/Final Visit	n	%
Low	Low	1	50.0
	Normal	1	50.0
	Total Reported	2	100.0
Normal	Low	6	5.8
	Normal	92	89.3
	High	4	3.9
	Not Done	1	1.0
	Total Reported	103	100.0
	Not Reported	14	
High	Low	1	12.5
	Normal	4	50.0
	High	3	37.5

(CONTINUED)

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Glucose (MG/DL)

Screen	Week 8/Final Visit	n	%
High	Total Reported	8	100.0
	Not Reported	1	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Chloride (MEQ/L)

Screen	Week 8/Final Visit	n	%
Normal	Normal	108	96.4
	High	3	2.7
	Not Done	1	0.9
	Total Reported	112	100.0
	Not Reported	15	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Urea Nitrogen (MG/DL)

Screen	Week 8/Final Visit	n	%
Low	Normal	3	100.0
	Total Reported	3	100.0
Normal	Low	2	1.8
	Normal	105	96.3
	High	1	0.9
	Not Done	1	0.9
	Total Reported	109	100.0
	Not Reported	14	
High	Normal	1	100.0
	Total Reported	1	100.0
	Not Reported	1	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Sodium (MEQ/L)

Screen	Week 8/Final Visit	n	%
Low	Low	1	100.0
	Total Reported	1	100.0
Normal	Low	1	0.9
	Normal	107	97.3
	High	1	0.9
	Not Done	1	0.9
	Total Reported	110	100.0
	Not Reported	15	
High	Normal	2	100.0
	Total Reported	2	100.0

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Potassium (MEQ/L)

Screen	Week 8/Final Visit	n	%
Normal	Low	2	1.8
	Normal	109	96.5
	High	1	0.9
	Not Done	1	0.9
	Total Reported	113	100.0
	Not Reported	15	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: TSH (UIU/ML)

Screen	Week 8/Final Visit	n	%
Low	Not Reported	2	
Normal	Normal	1	100.0
	Total Reported	1	100.0
	Not Reported	121	
High	Not Reported	4	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Reticulocyte Count (%)

Screen	Week 8/Final Visit	n	%
Normal	Low	2	1.9
	Normal	103	96.3
	Not Done	2	1.9
	Total Reported	107	100.0
	Not Reported	15	
High	Normal	2	66.7
	High	1	33.3
	Total Reported	3	100.0
Total Reported	Normal	2	66.7
	High	1	33.3
	Total Reported	3	100.0

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: T-4 (Thyroxine) (MCG/DL)

Screen	Week 8/Final Visit	n	%
Normal	Normal	1	100.0
	Total Reported	1	100.0
	Not Reported	127	

Table LAB7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Shift Frequencies from Screen to End of Week 8 - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: CO2 Content (MEQ/L)

Screen	Week 8/Final Visit	n	%
Low	Normal	2	100.0
	Total Reported	2	100.0
Normal	Low	2	1.8
	Normal	106	96.4
	High	1	0.9
	Not Done	1	0.9
	Total Reported	110	100.0
	Not Reported	15	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Alkaline Phosphase (U/L)	Mean	75.0	66.2	72.7	64.7
	SD	23.1	18.4	26.2	19.1
	n	23	22	21	21
	Median	70	64	65	62
	Min	44.0	36.0	43.0	34.0
	Max	141.0	108.0	150.0	105.0
Bilirubin, Total (MG/DL)	Mean	0.6	0.6	0.5	0.5
	SD	0.6	0.3	0.2	0.3
	n	23	22	21	21
	Median	0	0	0	0
	Min	0.2	0.2	0.2	0.2
	Max	3.1	1.3	1.2	1.5

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
ASAT (SGOT) (U/L)	Mean	18.5	19.5	18.2	20.0
	SD	4.6	7.4	7.0	5.3
	n	23	22	21	21
	Median	18	17	16	18
	Min	12.0	11.0	12.0	13.0
	Max	32.0	40.0	42.0	33.0
ALAT (SGPT) (U/L)	Mean	22.4	23.2	19.3	22.4
	SD	9.1	16.6	6.0	13.5
	n	23	22	21	21
	Median	18	18	18	17
	Min	12.0	9.0	12.0	10.0
	Max	43.0	68.0	32.0	53.0

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Uric Acid (MG/DL)	Mean	4.5	4.1	4.5	4.2
	SD	1.3	1.5	1.1	1.9
	n	23	22	21	21
	Median	4	4	4	4
	Min	2.1	1.9	2.9	1.7
	Max	6.3	7.3	6.4	9.9
Creatinine (MG/DL)	Mean	0.8	0.8	0.8	0.8
	SD	0.2	0.2	0.2	0.2
	n	23	22	21	21
	Median	0	0	0	0
	Min	0.6	0.4	0.5	0.4
	Max	1.3	1.2	1.1	1.1

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Glucose (MG/DL)	Mean	89.4	92.0	95.1	93.5
	SD	17.0	11.0	19.7	11.2
	n	23	22	20	21
	Median	88	93	89	94
	Min	60.0	72.0	54.0	75.0
	Max	131.0	111.0	147.0	117.0
Chloride (MEQ/L)	Mean	103.6	103.4	104.1	104.5
	SD	2.3	3.0	3.2	2.8
	n	23	22	21	21
	Median	104	103	104	104
	Min	97.0	98.0	98.0	101.0
	Max	107.0	109.0	111.0	110.0

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Urea Nitrogen (MG/DL)	Mean	13.9	14.2	13.7	14.2
	SD	3.6	4.0	3.7	4.6
	n	23	22	21	21
	Median	14	14	14	14
	Min	7.0	7.0	7.0	5.0
	Max	23.0	22.0	22.0	25.0
Sodium (MEQ/L)	Mean	140.2	139.8	140.0	141.2
	SD	2.1	2.2	2.2	2.3
	n	23	22	21	21
	Median	140	140	140	142
	Min	136.0	134.0	136.0	138.0
	Max	143.0	143.0	144.0	145.0

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Potassium (MEQ/L)	Mean	4.3	4.2	4.4	4.2
	SD	0.3	0.4	0.4	0.4
	n	23	22	21	21
	Median	4	4	4	4
	Min	3.8	3.2	3.9	3.6
	Max	5.0	4.9	5.0	5.2
TSH (UIU/ML)	Mean			3.1	
	SD				
	n			1	
	Median			3	
	Min			3.1	
	Max			3.1	

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Reticulocyte Count (%)	Mean	1.7	1.6	1.5	1.8
	SD	0.6	0.8	0.4	0.8
	n	23	22	20	21
	Median	1	1	1	1
	Min	0.5	0.8	0.8	0.8
	Max	2.6	3.8	2.2	4.3
T-4 (Thyroxine) (MCG/DL)	Mean			7.2	
	SD				
	n			1	
	Median			7	
	Min			7.2	
	Max			7.2	

(CONTINUED)

Table LAB8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Serum Chemistry: Summary Statistics by Treatment Group and Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
CO2 Content (MEQ/L)	Mean	26.4	26.9	26.5	26.0
	SD	2.7	2.8	2.6	3.0
	n	23	22	21	21
	Median	27	27	26	26
	Min	22.0	22.0	22.0	20.0
	Max	32.0	30.0	31.0	31.0

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
Appearance	Clear	114	89.1	74	82.2	87	79.8
	Cloudy	1	0.8	6	6.7	5	4.6
	Hazy	13	10.2	8	8.9	13	11.9
	Turbid			2	2.2	4	3.7
	Total Reported	128	100.0	90	100.0	109	100.0
Urine Color	Dark Yellow	3	2.3	1	1.1	2	1.8
	Straw	4	3.1	1	1.1	1	0.9
	Yellow	121	94.5	88	97.8	105	96.3
	Colorless					1	0.9
	Total Reported	128	100.0	90	100.0	109	100.0
Protein, Qualitative	Negative	115	89.8	80	88.9	95	87.2
	Trace	11	8.6	10	11.1	11	10.1

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
Protein, Qualitative	1+	2	1.6			2	1.8
	2+					1	0.9
	Total Reported	128	100.0	90	100.0	109	100.0
Blood (Occult)	Negative	122	95.3	86	95.6	103	94.5
	Trace	2	1.6			2	1.8
	1+	2	1.6	1	1.1		
	2+	1	0.8	2	2.2		
	3+	1	0.8	1	1.1	4	3.7
	Total Reported	128	100.0	90	100.0	109	100.0
Glucose	Negative	127	99.2	90	100.0	109	100.0
	1+ OR 1/4 G/DL (%)	1	0.8				
	Total Reported	128	100.0	90	100.0	109	100.0

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
Urine Ketones	Negative	119	93.0	86	95.6	104	95.4
	Trace	4	3.1	4	4.4	3	2.8
	1+	5	3.9			2	1.8
	Total Reported	128	100.0	90	100.0	109	100.0
Bilirubin	Negative	128	100.0	90	100.0	108	99.1
	1+					1	0.9
	Total Reported	128	100.0	90	100.0	109	100.0
Nitrite	Negative	128	100.0	90	100.0	107	98.2
	Positive					2	1.8
	Total Reported	128	100.0	90	100.0	109	100.0
Leukocytes	Negative	115	89.8	76	84.4	95	87.2
	Trace	8	6.3	4	4.4	5	4.6

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
Leukocytes	1+	3	2.3	4	4.4	4	3.7
	2+	2	1.6	5	5.6	3	2.8
	3+			1	1.1	2	1.8
	Total Reported	128	100.0	90	100.0	109	100.0
Urobilinogen	0.2	120	93.8	87	96.7	105	97.2
	1	7	5.5	3	3.3	3	2.8
	2	1	0.8				
	Total Reported	128	100.0	90	100.0	108	100.0
Specific Gravity	1.005	6	4.7	7	7.8	10	9.2
	1.01	30	23.4	12	13.3	17	15.6
	1.015	25	19.5	15	16.7	28	25.7
	1.02	24	18.8	17	18.9	14	12.8

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
Specific Gravity	1.025	25	19.5	25	27.8	26	23.9
	1.03	18	14.1	14	15.6	14	12.8
	Total Reported	128	100.0	90	100.0	109	100.0
PH (Urine Reaction)	5.5	1	0.8				
	6	3	2.3	8	8.9	10	9.2
	6.5	18	14.1	25	27.8	21	19.3
	7	33	25.8	26	28.9	26	23.9
	7.5	50	39.1	20	22.2	33	30.3
	8	17	13.3	7	7.8	9	8.3
	8.5	6	4.7	4	4.4	10	9.2
	Total Reported	128	100.0	90	100.0	109	100.0
RBC/HPF	0-1	8	6.3	4	4.4	2	1.9

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
RBC/HPF	1-3	4	3.1	1	1.1	4	3.7
	3-5	2	1.6	2	2.2	1	0.9
	5-10	1	0.8			1	0.9
	10-15			1	1.1		
	15-25			1	1.1		
	25-50	1	0.8			2	1.9
	None seen	112	87.5	81	90.0	96	89.7
	Innumerable					1	0.9
	Total Reported	128	100.0	90	100.0	107	100.0
WBC/HPF	0-1	39	30.5	32	35.6	35	32.4
	1-3	40	31.3	24	26.7	32	29.6
	3-5	10	7.8	7	7.8	5	4.6

(CONTINUED)

Table LAB9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 4		Week 8/Final	
		n	%	n	%	n	%
WBC/HPF	5-10			5	5.6	3	2.8
	10-15	1	0.8	5	5.6	2	1.9
	15-25			1	1.1	3	2.8
	None seen	38	29.7	16	17.8	27	25.0
	Innumerable					1	0.9
	Total Reported	128	100.0	90	100.0	108	100.0
Microscopic Findings Other than Urine RBCs & WBCs	Negative	18	14.1	3	3.3	11	10.2
	Positive	110	85.9	87	96.7	97	89.8
	Total Reported	128	100.0	90	100.0	108	100.0

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Appearance

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	2	15.4
	Normal	11	84.6
	Total Reported	13	100.0
Normal	Abnormal	20	20.8
	Normal	76	79.2
	Total Reported	96	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Urine Color

Screen	Week 8/Final Visit	n	%
Abnormal	Normal	2	100.0
	Total Reported	2	100.0
Normal	Abnormal	3	2.8
	Normal	104	97.2
	Total Reported	107	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Protein, Qualitative

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	3	27.3
	Normal	8	72.7
	Total Reported	11	100.0
Normal	Abnormal	11	11.2
	Normal	87	88.8
	Total Reported	98	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Blood (Occult)

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	1	20.0
	Normal	4	80.0
	Total Reported	5	100.0
Normal	Abnormal	5	4.8
	Normal	99	95.2
	Total Reported	104	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Glucose

Screen	Week 8/Final Visit	n	%
Abnormal	Normal	1	100.0
	Total Reported	1	100.0
Normal	Normal	108	100.0
	Total Reported	108	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Urine Ketones

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	1	20.0
	Normal	4	80.0
	Total Reported	5	100.0
Normal	Abnormal	4	3.8
	Normal	100	96.2
	Total Reported	104	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Bilirubin

Screen	Week 8/Final Visit	n	%
Normal	Abnormal	1	0.9
	Normal	108	99.1
	Total Reported	109	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Nitrite

Screen	Week 8/Final Visit	n	%
Normal	Abnormal	2	1.8
	Normal	107	98.2
	Total Reported	109	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Leukocytes

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	4	40.0
	Normal	6	60.0
	Total Reported	10	100.0
	Not Reported	2	
Normal	Abnormal	10	10.1
	Normal	89	89.9
	Total Reported	99	100.0
	Not Reported	2	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Urobilinogen

Screen	Week 8/Final Visit	n	%
Normal	Normal	107	100.0
	Total Reported	107	100.0
	Not Reported	5	
High	Normal	1	100.0
	Total Reported	1	100.0

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Specific Gravity

Screen	Week 8/Final Visit	n	%
Normal	Normal	109	100.0
	Total Reported	109	100.0
	Not Reported	4	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: PH (Urine Reaction)

Screen	Week 8/Final Visit	n	%
Normal	Normal	97	93.3
	High	7	6.7
	Total Reported	104	100.0
	Not Reported	3	
High	Normal	2	40.0
	High	3	60.0
	Total Reported	5	100.0
	Not Reported	1	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: RBC/HPF

Screen	Week 8/Final Visit	n	%
Abnormal	Normal	3	100.0
	Total Reported	3	100.0
	Not Reported	1	
Normal	Abnormal	5	4.8
	Normal	99	95.2
	Total Reported	104	100.0
	Not Reported	5	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: WBC/HPF

Screen	Week 8/Final Visit	n	%
Abnormal	Normal	1	100.0
	Total Reported	1	100.0
Normal	Abnormal	6	5.6
	Normal	101	94.4
	Total Reported	107	100.0
	Not Reported	5	

Table LAB10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Shift Frequencies from Screen to End of Week 8, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay: Microscopic Findings Other than Urine RBCs & WBCs

Screen	Week 8/Final Visit	n	%
Abnormal	Abnormal	82	88.2
	Normal	11	11.8
	Total Reported	93	100.0
	Not Reported	5	
Normal	Abnormal	15	100.0
	Total Reported	15	100.0

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Appearance	Clear	18	78.3	19	90.5	19	95.0	19	90.5
	Cloudy	1	4.3						
	Hazy	3	13.0	2	9.5	1	5.0	2	9.5
	Turbid	1	4.3						
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Urine Color	Colorless	1	4.3						
	Yellow	22	95.7	21	100.0	20	100.0	21	100.0
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Protein, Qualitative	Negative	21	91.3	17	81.0	20	100.0	19	90.5
	Trace	2	8.7	4	19.0			1	4.8
	1+							1	4.8

(CONTINUED)

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Protein, Qualitative	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Blood (Occult)	Negative	23	100.0	21	100.0	19	95.0	21	100.0
	Trace					1	5.0		
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Glucose	Negative	23	100.0	21	100.0	20	100.0	21	100.0
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Urine Ketones	Negative	22	95.7	19	90.5	19	95.0	19	90.5
	Trace	1	4.3	1	4.8	1	5.0	1	4.8
	1+			1	4.8			1	4.8
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Bilirubin	Negative	23	100.0	20	95.2	20	100.0	21	100.0

(CONTINUED)

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Bilirubin	1+			1	4.8				
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Nitrite	Negative	23	100.0	21	100.0	20	100.0	21	100.0
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Leukocytes	Negative	20	87.0	20	95.2	18	90.0	20	95.2
	Trace			1	4.8				
	1+	2	8.7			2	10.0	1	4.8
	2+	1	4.3						
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
Urobilinogen	0.2	22	100.0	20	95.2	20	100.0	20	95.2
	1			1	4.8			1	4.8

(CONTINUED)

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Urobilinogen	Total Reported	22	100.0	21	100.0	20	100.0	21	100.0
Specific Gravity	1.005	4	17.4			1	5.0	1	4.8
	1.01	4	17.4	3	14.3	7	35.0	2	9.5
	1.015	5	21.7	7	33.3	3	15.0	2	9.5
	1.02	5	21.7	2	9.5	5	25.0	5	23.8
	1.025	2	8.7	4	19.0	1	5.0	5	23.8
	1.03	3	13.0	5	23.8	3	15.0	6	28.6
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
PH (Urine Reaction)	6			2	9.5	1	5.0		
	6.5	4	17.4	6	28.6	4	20.0	6	28.6
	7	7	30.4	5	23.8	6	30.0	7	33.3

(CONTINUED)

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
PH (Urine Reaction)	7.5	7	30.4	5	23.8	7	35.0	5	23.8
	8	2	8.7	1	4.8	1	5.0	2	9.5
	8.5	3	13.0	2	9.5	1	5.0	1	4.8
	Total Reported	23	100.0	21	100.0	20	100.0	21	100.0
RBC/HPF	0-1	1	4.3			1	5.0	1	5.3
	1-3	1	4.3	1	4.8				
	None Seen	21	91.3	20	95.2	19	95.0	18	94.7
	Total Reported	23	100.0	21	100.0	20	100.0	19	100.0
WBC/HPF	0-1	8	34.8	6	28.6	9	45.0	5	25.0
	1-3	3	13.0	8	38.1	1	5.0	11	55.0
	3-5	1	4.3			2	10.0	1	5.0

(CONTINUED)

Table LAB11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urinalysis: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
WBC/HPF	5-10	1	4.3			1	5.0	1	5.0
	10-15					1	5.0		
	15-25	2	8.7						
	None Seen	8	34.8	7	33.3	6	30.0	2	10.0
	Total Reported	23	100.0	21	100.0	20	100.0	20	100.0
Microscopic Findings Other than Urine RBCs & WBCs	Negative	3	13.0	4	19.0	3	15.0	2	10.0
	Positive	20	87.0	17	81.0	17	85.0	18	90.0
	Total Reported	23	100.0	21	100.0	20	100.0	20	100.0

Table LAB12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 8/Final	
		n	%	n	%
Amphetaimes	Negative	127	99.2	107	99.1
	Positives	1	0.8	1	0.9
	Total Reported	128	100.0	108	100.0
Barbiturates	Negative	128	100.0	107	99.1
	Positives			1	0.9
	Total Reported	128	100.0	108	100.0
Benzodiazepines	Negative	124	96.9	103	95.4
	Positives	4	3.1	5	4.6
	Total Reported	128	100.0	108	100.0
Cocaine Metabolites	Negative	128	100.0	107	99.1
	Positives			1	0.9
	Total Reported	128	100.0	108	100.0

(CONTINUED)

Table LAB12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 8/Final	
		n	%	n	%
Marijuana Metabolites	Negative	127	99.2	107	99.1
	Positives	1	0.8	1	0.9
	Total Reported	128	100.0	108	100.0
Methadone	Negative	128	100.0	108	100.0
	Total Reported	128	100.0	108	100.0
Methaqualone	Negative	128	100.0	108	100.0
	Total Reported	128	100.0	108	100.0
Opiates	Negative	124	96.9	106	98.1
	Positives	4	3.1	2	1.9
	Total Reported	128	100.0	108	100.0
Phencyclidine	Negative	128	100.0	108	100.0
	Total Reported	128	100.0	108	100.0

(CONTINUED)

Table LAB12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Screen		Week 8/Final	
		n	%	n	%
Proproxyphene	Negative	126	98.4	107	99.1
	Positives	2	1.6	1	0.9
	Total Reported	128	100.0	108	100.0

Table LAB13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Amphetaimes	Negative	23	100.0	20	100.0	19	100.0	21	100.0
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Barbiturates	Negative	23	100.0	19	95.0	19	100.0	21	100.0
	Positives			1	5.0				
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Benzodiazepines	Negative	23	100.0	19	95.0	19	100.0	21	100.0
	Positives			1	5.0				
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Cocaine Metabolites	Negative	23	100.0	20	100.0	19	100.0	21	100.0
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Marijuana Metabolites	Negative	23	100.0	20	100.0	19	100.0	21	100.0

(CONTINUED)

Table LAB13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Marijuana Metabolites	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Methadone	Negative	23	100.0	20	100.0	19	100.0	21	100.0
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Methaqualone	Negative	23	100.0	20	100.0	19	100.0	21	100.0
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Opiates	Negative	23	100.0	20	100.0	19	100.0	20	95.2
	Positives							1	4.8
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Phencyclidine	Negative	23	100.0	20	100.0	19	100.0	21	100.0
	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0
Proproxyphene	Negative	23	100.0	20	100.0	19	100.0	21	100.0

(CONTINUED)

Table LAB13

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Urine Drug Screen: Summary by Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Assay		Week 8				Week 32/Final Visit			
		RBX		Placebo		RBX		Placebo	
		n	%	n	%	n	%	n	%
Proproxyphene	Total Reported	23	100.0	20	100.0	19	100.0	21	100.0

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Basophils (%)	Liebowitz	91097	RBX	38/Female	Screen	0.0	2.0	%	0.1	N
					Week 4	0.0	2.0	%	2.3	H
					Week 8	0.0	2.0	%	0.4	N
Eosinophils (%)	Delgado	41069	RBX	41/Female	Screen	0.0	7.0	%	5.6	N
					Week 4	0.0	7.0	%	9.3	H
					Week 8	0.0	7.0	%	8.2	H
					Wk 32/Final Visit	0.0	7.0	%	13.1	H
	Fava	51114	RBX	54/Female	Screen	0.0	7.0	%	3.2	N
					Week 4	0.0	7.0	%	7.2	H
	Helfing	81076	RBX	23/Female	Screen	0.0	7.0	%	1.6	N
					Week 4	0.0	7.0	%	10.5	H
					Week 8	0.0	7.0	%	1.2	N
					Wk 32/Final Visit	0.0	7.0	%	2.0	N
	Liebowitz	91005	RBX	54/Female	Screen	0.0	7.0	%	7.6	H
					Week 8	0.0	7.0	%	7.8	H
		91137	RBX	40/Male	Screen	0.0	7.0	%	3.1	N
					Week 4	0.0	7.0	%	7.6	H
					Week 8	0.0	7.0	%	3.1	N
	Munjack	131144	RBX	33/Female	Screen	0.0	7.0	%	7.2	H
					Week 4	0.0	7.0	%	4.9	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Eosinophils (%)	Munjack	131144	RBX	33/Female	Week 8	0.0	7.0	%	9.6	H
	Oldroyd	321055	RBX	38/Male	Screen	0.0	7.0	%	2.0	N
					Week 4	0.0	7.0	%	8.3	H
	Rapaport	151096	Placebo	60/Male	Screen	0.0	7.0	%	3.2	N
					Week 4	0.0	7.0	%	4.4	N
					Week 8	0.0	7.0	%	2.8	N
					Wk 32/Final Visit	0.0	7.0	%	18.8	H
	Thase	181084	Placebo	32/Male	Screen	0.0	7.0	%	4.2	N
					Week 4	0.0	7.0	%	7.5	H
					Week 8	0.0	7.0	%	5.7	N
					Wk 32/Final Visit	0.0	7.0	%	3.3	N
		181135	RBX	31/Female	Screen	0.0	7.0	%	4	N
					Week 4	0.0	7.0	%	4.4	N
					Week 8	0.0	7.0	%	7.5	H
					Unscheduled	0.0	7.0	%	12.8	H
	Walsh	171062	Placebo	52/Female	Screen	0.0	7.0	%	0.6	N
					Week 4	0.0	7.0	%	8.3	H
					Week 8	0.0	7.0	%	2.7	N
					Wk 32/Final Visit	0.0	7.0	%	2.3	N
Hematocrit (%)	Amsterdam	11133	RBX	41/Male	Screen	41.0	50.0	%	44.8	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hematocrit (%)	Amsterdam	11133	RBX	41/Male	Week 4	41.0	50.0	%	39.9	L
					Week 8	41.0	50.0	%	43.6	N
		11134	RBX	49/Male	Screen	41.0	50.0	%	35.4	L
					Week 4	41.0	50.0	%	33.7	L
					Week 8	41.0	50.0	%	39.0	L
	Clayton	31019	RBX	45/Male	Screen	41.0	50.0	%	41.3	N
					Week 4	41.0	50.0	%	39.9	L
					Week 8	41.0	50.0	%	42.1	N
					Wk 32/Final Visit	41.0	50.0	%	43.0	N
	Croft	231002	RBX	40/Female	Screen	35.0	46.0	%	39.9	N
					Unscheduled	35.0	46.0	%	31.6	L
		231080	RBX	55/Female	Screen	35.0	46.0	%	35.4	N
					Week 4	35.0	46.0	%	34.0	L
					Week 8	35.0	46.0	%	36.9	N
	Dunner	211145	RBX	41/Male	Screen	41.0	50.0	%	43.3	N
					Week 8	41.0	50.0	%	40.3	L
	Fava	51114	RBX	54/Female	Screen	35.0	46.0	%	37.4	N
					Week 4	35.0	46.0	%	33.3	L
		51142	RBX	44/Female	Screen	35.0	46.0	%	36.4	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hematocrit (%)	Fava	51142	RBX	44/Female	Week 4	35.0	46.0	%	33.2	L
					Week 8	35.0	46.0	%	32.4	L
	Ferguson	241073	RBX	26/Female	Screen	35.0	46.0	%	44.2	N
					Week 4	35.0	46.0	%	44.8	N
					Week 8	35.0	46.0	%	46.8	H
	Liebowitz	91097	RBX	38/Female	Screen	35.0	46.0	%	35.1	N
					Week 4	35.0	46.0	%	33.5	L
					Week 8	35.0	46.0	%	33.6	L
	Londborg	101044	Placebo	41/Female	Screen	35.0	46.0	%	36.8	N
					Week 4	35.0	46.0	%	35.9	N
					Week 8	35.0	46.0	%	39.0	N
					Wk 32/Final Visit	35.0	46.0	%	34.9	L
	Lydiard	221034	RBX	40/Female	Screen	35.0	46.0	%	28.0	L
					Week 4	35.0	46.0	%	29.1	L
					Week 8	35.0	46.0	%	30.0	L
	McGrath	111058	RBX	20/Female	Screen	35.0	46.0	%	33.8	L
					Week 4	35.0	46.0	%	33.6	L
					Week 8	35.0	46.0	%	31.9	L
					Unscheduled	35.0	46.0	%	33.4	L
	Munjack	131072	RBX	58/Male	Screen	41.0	50.0	%	42.5	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hematocrit (%)	Munjack	131072	RBX	58/Male	Week 4	41.0	50.0	%	40.7	L
					Week 8	41.0	50.0	%	39.1	L
		131126	RBX	45/Male	Screen	41.0	50.0	%	48.2	N
					Week 4	41.0	50.0	%	47.5	N
					Week 8	41.0	50.0	%	50.3	H
	Oldroyd	321087	RBX	55/Male	Screen	41.0	50.0	%	43.7	N
					Week 4	41.0	50.0	%	39.4	L
					Week 8	41.0	50.0	%	40.9	L
					Wk 32/Final Visit	41.0	50.0	%	44.6	N
	Rapaport	151095	RBX	49/Male	Screen	41.0	50.0	%	50.0	N
					Week 4	41.0	50.0	%	48.3	N
					Week 8	41.0	50.0	%	46.3	N
					Wk 32/Final Visit	41.0	50.0	%	50.7	H
	Thase	181083	RBX	58/Male	Screen	41.0	50.0	%	39.9	L
					Week 4	41.0	50.0	%	39.1	L
					Week 8	41.0	50.0	%	39.4	L
					Wk 32/Final Visit	41.0	50.0	%	41.5	N
		181135	RBX	31/Female	Screen	35.0	46.0	%	35.1	N
					Week 4	35.0	46.0	%	34.8	L
					Week 8	35.0	46.0	%	35.5	N
					Unscheduled	35.0	46.0	%	37.4	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hemoglobin (G/DL)	Amsterdam	11134	RBX	49/Male	Screen	13.8	17.2	G/DL	11.6	L
					Week 4	13.8	17.2	G/DL	10.8	L
					Week 8	13.8	17.2	G/DL	12.9	L
	Clayton	31019	RBX	45/Male	Screen	13.8	17.2	G/DL	13.2	L
					Week 4	13.8	17.2	G/DL	13.1	L
					Week 8	13.8	17.2	G/DL	13.3	L
					Wk 32/Final Visit	13.8	17.2	G/DL	14.7	N
		31112	RBX	44/Female	Screen	12.0	15.6	G/DL	13.6	N
					Week 4	12.0	15.6	G/DL	12.8	N
					Week 8	12.0	15.6	G/DL	11.2	L
	Croft	231002	RBX	40/Female	Screen	12.0	15.6	G/DL	13.9	N
					Unscheduled	12.0	15.6	G/DL	11.0	L
		231080	RBX	55/Female	Screen	12.0	15.6	G/DL	11.8	L
					Week 4	12.0	15.6	G/DL	11.6	L
					Week 8	12.0	15.6	G/DL	12.4	N
	Dunner	211145	RBX	41/Male	Screen	13.8	17.2	G/DL	14.7	N
					Week 8	13.8	17.2	G/DL	13.7	L
	Fava	51114	RBX	54/Female	Screen	12.0	15.6	G/DL	12.4	N
					Week 4	12.0	15.6	G/DL	11.1	L

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hemoglobin (G/DL)	Fava	51142	RBX	44/Female	Screen	12.0	15.6	G/DL	11.7	L
					Week 4	12.0	15.6	G/DL	11.2	L
					Week 8	12.0	15.6	G/DL	10.3	L
	Ferguson	241073	RBX	26/Female	Screen	12.0	15.6	G/DL	15.5	N
					Week 4	12.0	15.6	G/DL	15.3	N
					Week 8	12.0	15.6	G/DL	15.7	H
	Helfing	81076	RBX	23/Female	Screen	12.0	15.6	G/DL	15.8	H
					Week 4	12.0	15.6	G/DL	14.7	N
					Week 8	12.0	15.6	G/DL	15.8	H
					Wk 32/Final Visit	12.0	15.6	G/DL	14.8	N
	Liebowitz	91097	RBX	38/Female	Screen	12.0	15.6	G/DL	11.4	L
					Week 4	12.0	15.6	G/DL	11.2	L
					Week 8	12.0	15.6	G/DL	11.1	L
	Londborg	101044	Placebo	41/Female	Screen	12.0	15.6	G/DL	12.3	N
					Week 4	12.0	15.6	G/DL	11.9	L
					Week 8	12.0	15.6	G/DL	12.6	N
					Wk 32/Final Visit	12.0	15.6	G/DL	11.7	L
	Lydiard	221034	RBX	40/Female	Screen	12.0	15.6	G/DL	8.9	L
					Week 4	12.0	15.6	G/DL	9.1	L
					Week 8	12.0	15.6	G/DL	9.7	L

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hemoglobin (G/DL)	McGrath	111058	RBX	20/Female	Screen	12.0	15.6	G/DL	10.8	L
					Week 4	12.0	15.6	G/DL	11.1	L
					Week 8	12.0	15.6	G/DL	10.5	L
					Unscheduled	12.0	15.6	G/DL	10.6	L
	Munjack	131126	RBX	45/Male	Screen	13.8	17.2	G/DL	16.2	N
					Week 4	13.8	17.2	G/DL	16.3	N
					Week 8	13.8	17.2	G/DL	17.3	H
		131143	RBX	39/Female	Screen	12.0	15.6	G/DL	10.5	L
					Week 4	12.0	15.6	G/DL	11.9	L
					Week 8	12.0	15.6	G/DL	12.6	N
	Oldroyd	321087	RBX	55/Male	Screen	13.8	17.2	G/DL	14.9	N
					Week 4	13.8	17.2	G/DL	13.4	L
					Week 8	13.8	17.2	G/DL	13.9	N
					Wk 32/Final Visit	13.8	17.2	G/DL	15.5	N
	Thase	181083	RBX	58/Male	Screen	13.8	17.2	G/DL	13.5	L
					Week 4	13.8	17.2	G/DL	12.8	L
					Week 8	13.8	17.2	G/DL	13.3	L
					Wk 32/Final Visit	13.8	17.2	G/DL	13.8	N
		181135	RBX	31/Female	Screen	12.0	15.6	G/DL	11.7	L
					Week 4	12.0	15.6	G/DL	11.8	L
					Week 8	12.0	15.6	G/DL	12.0	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Hemoglobin (G/DL)	Thase	181135	RBX	31/Female	Unscheduled	12.0	15.6	G/DL	12.1	N
Lymphocytes (%)	Amsterdam	11133	RBX	41/Male	Screen	16.0	46.0	%	7	L
					Week 4	16.0	46.0	%	21.7	N
					Week 8	16.0	46.0	%	8	L
	Clayton	31020	Placebo	55/Male	Screen	16.0	46.0	%	26.5	N
					Week 4	16.0	46.0	%	44.8	N
					Week 8	16.0	46.0	%	44.9	N
					Wk 32/Final Visit	16.0	46.0	%	50.6	H
	Croft	231002	RBX	40/Female	Screen	16.0	46.0	%	26.3	N
					Unscheduled	16.0	46.0	%	15	L
		231120	RBX	54/Female	Screen	16.0	46.0	%	38.0	N
					Week 4	16.0	46.0	%	36.0	N
					Week 8	16.0	46.0	%	38.6	N
					Wk 32/Final Visit	16.0	46.0	%	49.0	H
	Dunner	211146	RBX	57/Male	Screen	16.0	46.0	%	46.8	H
					Week 4	16.0	46.0	%	48.1	H
					Week 8	16.0	46.0	%	42.2	N
		211147	RBX	37/Female	Screen	16.0	46.0	%	16	N
					Week 8	16.0	46.0	%	14.1	L

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Lymphocytes (%)	Helfing	81003	Placebo	65/Female	Screen	16.0	46.0	%	24.8	N
					Week 4	16.0	46.0	%	38.7	N
					Week 8	16.0	46.0	%	52.7	H
					Unscheduled	16.0	46.0	%	40.2	N
		81076	RBX	23/Female	Screen	16.0	46.0	%	36.8	N
					Week 4	16.0	46.0	%	53.2	H
					Week 8	16.0	46.0	%	30.7	N
					Wk 32/Final Visit	16.0	46.0	%	36.6	N
	Liebowitz	91035	RBX	62/Female	Screen	16.0	46.0	%	31.4	N
					Week 4	16.0	46.0	%	39.0	N
					Week 8	16.0	46.0	%	50.4	H
	Londborg	101010	RBX	51/Female	Screen	16.0	46.0	%	38.3	N
					Week 4	16.0	46.0	%	46.0	N
					Week 8	16.0	46.0	%	47.0	H
	McGrath	111058	RBX	20/Female	Screen	16.0	46.0	%	51.2	H
					Week 4	16.0	46.0	%	38.9	N
					Week 8	16.0	46.0	%	34.5	N
					Unscheduled	16.0	46.0	%	46.7	H
	Oldroyd	321087	RBX	55/Male	Screen	16.0	46.0	%	26.9	N
					Week 4	16.0	46.0	%	30.1	N
					Week 8	16.0	46.0	%	14.6	L

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Lymphocytes (%)	Oldroyd	321087	RBX	55/Male	Wk 32/Final Visit	16.0	46.0	%	23.3	N
	Rapaport	151038	Placebo	52/Male	Screen	16.0	46.0	%	36.4	N
					Week 4	16.0	46.0	%	39.6	N
					Week 8	16.0	46.0	%	39.7	N
					Wk 32/Final Visit	16.0	46.0	%	49.3	H
		151095	RBX	49/Male	Screen	16.0	46.0	%	17.7	N
					Week 4	16.0	46.0	%	26.5	N
					Week 8	16.0	46.0	%	13.7	L
					Wk 32/Final Visit	16.0	46.0	%	12	L
	Smith	281101	RBX	40/Female	Screen	16.0	46.0	%	34.5	N
					Week 4	16.0	46.0	%	46.8	H
					Week 8	16.0	46.0	%	40.1	N
	Walsh	171062	Placebo	52/Female	Screen	16.0	46.0	%	39.4	N
					Week 4	16.0	46.0	%	36.7	N
					Week 8	16.0	46.0	%	46.6	H
					Wk 32/Final Visit	16.0	46.0	%	45.9	N
		171063	Placebo	27/Male	Screen	16.0	46.0	%	28.3	N
					Week 4	16.0	46.0	%	30.4	N
					Week 8	16.0	46.0	%	48.6	H
					Wk 32/Final Visit	16.0	46.0	%	28.8	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
MCV (FL)	Fava	51142	RBX	44/Female	Screen	80	100	FL	81	N
					Week 4	80	100	FL	79	L
					Week 8	80	100	FL	81	N
	Lydiard	221034	RBX	40/Female	Screen	80	100	FL	74	L
					Week 4	80	100	FL	73	L
					Week 8	80	100	FL	74	L
	McGrath	111058	RBX	20/Female	Screen	80	100	FL	75	L
					Week 4	80	100	FL	77	L
					Week 8	80	100	FL	79	L
					Unscheduled	80	100	FL	76	L
	Munjack	131143	RBX	39/Female	Screen	80	100	FL	78	L
					Week 4	80	100	FL	76	L
					Week 8	80	100	FL	78	L
	Smith	281101	RBX	40/Female	Screen	80	100	FL	101	H
					Week 4	80	100	FL	101	H
					Week 8	80	100	FL	102	H
Monocytes (%)	Croft	231002	RBX	40/Female	Screen	0.0	12.0	%	7.8	N
					Unscheduled	0.0	12.0	%	14	H
	DuBoff	311018	RBX	31/Female	Screen	0.0	12.0	%	8.5	N
					Week 4	0.0	12.0	%	13.5	H

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Monocytes (%)	DuBoff	311018	RBX	31/Female	Week 8	0.0	12.0	%	11.6	N
	Helfing	81003	Placebo	65/Female	Screen	0.0	12.0	%	6.4	N
					Week 4	0.0	12.0	%	12.3	H
					Week 8	0.0	12.0	%	10.8	N
					Unscheduled	0.0	12.0	%	10.1	N
		81052	RBX	39/Female	Screen	0.0	12.0	%	7.3	N
					Week 8	0.0	12.0	%	14.1	H
Platelet Counts (CMM)	Amsterdam	11133	RBX	41/Male	Screen	130000	400000	CMM	275000	N
					Week 4	130000	400000	CMM	297000	N
					Week 8	130000	400000	CMM	456000	H
		11134	RBX	49/Male	Screen	130000	400000	CMM	408000	H
					Week 4	130000	400000	CMM	443000	H
					Week 8	130000	400000	CMM	419000	H
	Clayton	31112	RBX	44/Female	Screen	130000	400000	CMM	373000	N
					Week 4	130000	400000	CMM	288000	N
					Week 8	130000	400000	CMM	422000	H
	Croft	231002	RBX	40/Female	Screen	130000	400000	CMM	279000	N
					Unscheduled	130000	400000	CMM	661000	H
		231120	RBX	54/Female	Screen	130000	400000	CMM	381000	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Platelet Counts (CMM)	Croft	231120	RBX	54/Female	Week 4	130000	400000	CMM	435000	H
					Week 8	130000	400000	CMM	396000	N
					Wk 32/Final Visit	130000	400000	CMM	391000	N
		231139	RBX	36/Female	Screen	130000	400000	CMM	326000	N
					Week 4	130000	400000	CMM	375000	N
					Week 8	130000	400000	CMM	405000	H
	Delgado	41093	RBX	56/Female	Screen	130000	400000	CMM	413000	H
					Week 4	130000	400000	CMM	429000	H
					Week 8	130000	400000	CMM	402000	H
					Wk 32/Final Visit	130000	400000	CMM	396000	N
	Dunner	211040	RBX	53/Female	Screen	130000	400000	CMM	397000	N
					Week 4	130000	400000	CMM	397000	N
					Week 8	130000	400000	CMM	408000	H
					Wk 32/Final Visit	130000	400000	CMM	427000	H
		211147	RBX	37/Female	Screen	130000	400000	CMM	484000	H
					Week 8	130000	400000	CMM	410000	H
	Fava	51114	RBX	54/Female	Screen	130000	400000	CMM	246000	N
					Week 4	130000	400000	CMM	417000	H
	Ferguson	241073	RBX	26/Female	Screen	130000	400000	CMM	367000	N
					Week 4	130000	400000	CMM	400000	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Platelet Counts (CMM)	Ferguson	241073	RBX	26/Female	Week 8	130000	400000	CMM	407000	H
	Oldroyd	321055	RBX	38/Male	Screen	130000	400000	CMM	385000	N
					Week 4	130000	400000	CMM	443000	H
	Rapaport	151117	RBX	49/Female	Screen	130000	400000	CMM	376000	N
					Week 4	130000	400000	CMM	425000	H
					Week 8	130000	400000	CMM	416000	H
	Walsh	171064	RBX	21/Female	Screen	130000	400000	CMM	483000	H
					Week 8	130000	400000	CMM	515000	H
Red Cell Count (M/UL)	Amsterdam	11134	RBX	49/Male	Screen	4.4	5.8	M/UL	3.8	L
					Week 4	4.4	5.8	M/UL	3.6	L
					Week 8	4.4	5.8	M/UL	4.3	L
	Clayton	31019	RBX	45/Male	Screen	4.4	5.8	M/UL	4.3	L
					Week 4	4.4	5.8	M/UL	4.3	L
					Week 8	4.4	5.8	M/UL	4.3	L
					Wk 32/Final Visit	4.4	5.8	M/UL	4.7	N
		31112	RBX	44/Female	Screen	3.9	5.2	M/UL	4.3	N
					Week 4	3.9	5.2	M/UL	4.0	N
					Week 8	3.9	5.2	M/UL	3.8	L
	Croft	231002	RBX	40/Female	Screen	3.9	5.2	M/UL	4.2	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Red Cell Count (M/UL)	Croft	231002	RBX	40/Female	Unscheduled	3.9	5.2	M/UL	3.3	L
		231080	RBX	55/Female	Screen	3.9	5.2	M/UL	3.6	L
					Week 4	3.9	5.2	M/UL	3.4	L
					Week 8	3.9	5.2	M/UL	3.7	L
	Fava	51114	RBX	54/Female	Screen	3.9	5.2	M/UL	4.1	N
					Week 4	3.9	5.2	M/UL	3.8	L
	Munjack	131072	RBX	58/Male	Screen	4.4	5.8	M/UL	4.9	N
					Week 4	4.4	5.8	M/UL	4.5	N
					Week 8	4.4	5.8	M/UL	4.3	L
	Oldroyd	321087	RBX	55/Male	Screen	4.4	5.8	M/UL	4.7	N
					Week 4	4.4	5.8	M/UL	4.2	L
					Week 8	4.4	5.8	M/UL	4.3	L
					Wk 32/Final Visit	4.4	5.8	M/UL	4.8	N
	Rapaport	151086	RBX	45/Female	Screen	3.9	5.2	M/UL	4.2	N
					Week 4	3.9	5.2	M/UL	3.8	L
					Week 8	3.9	5.2	M/UL	4.4	N
	Thase	181083	RBX	58/Male	Screen	4.4	5.8	M/UL	4.3	L
					Week 4	4.4	5.8	M/UL	4.2	L
					Week 8	4.4	5.8	M/UL	4.3	L
					Wk 32/Final Visit	4.4	5.8	M/UL	4.4	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Red Cell Count (M/UL)	Zajecka	201068	Placebo	37/Female	Screen	3.9	5.2	M/UL	3.9	N
					Week 4	3.9	5.2	M/UL	3.8	L
					Week 8	3.9	5.2	M/UL	3.7	L
					Wk 32/Final Visit	3.9	5.2	M/UL	3.8	L
Total Neutrophils (%)	Amsterdam	11133	RBX	41/Male	Screen	40.0	75.0	%	91	H
					Week 4	40.0	75.0	%	71.3	N
					Week 8	40.0	75.0	%	85	H
	Clayton	31020	Placebo	55/Male	Screen	40.0	75.0	%	65.8	N
					Week 4	40.0	75.0	%	38.9	L
					Week 8	40.0	75.0	%	40.7	N
					Wk 32/Final Visit	40.0	75.0	%	38.1	L
	Croft	231119	RBX	56/Female	Screen	40.0	75.0	%	65	N
					Week 4	40.0	75.0	%	76.5	H
					Week 8	40.0	75.0	%	65.4	N
					Wk 32/Final Visit	40.0	75.0	%	60.8	N
	Dunner	211146	RBX	57/Male	Screen	40.0	75.0	%	39.6	L
					Week 4	40.0	75.0	%	37.2	L
					Week 8	40.0	75.0	%	48.3	N
		211147	RBX	37/Female	Screen	40.0	75.0	%	78	H
					Week 8	40.0	75.0	%	82.4	H

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Total Neutrophils (%)	Helfing	81003	Placebo	65/Female	Screen	40.0	75.0	%	65.7	N
					Week 4	40.0	75.0	%	46.3	N
					Week 8	40.0	75.0	%	34.2	L
					Unscheduled	40.0	75.0	%	47.3	N
		81076	RBX	23/Female	Screen	40.0	75.0	%	59.0	N
					Week 4	40.0	75.0	%	29.9	L
					Week 8	40.0	75.0	%	63.4	N
					Wk 32/Final Visit	40.0	75.0	%	58.3	N
	Liebowitz	91035	RBX	62/Female	Screen	40.0	75.0	%	55.0	N
					Week 4	40.0	75.0	%	51.2	N
					Week 8	40.0	75.0	%	39.8	L
	Munjack	131125	Placebo	34/Female	Screen	40.0	75.0	%	84.8	H
					Week 4	40.0	75.0	%	80.3	H
					Week 8	40.0	75.0	%	74.0	N
					Wk 32/Final Visit	40.0	75.0	%	76.3	H
	Rapaport	151095	RBX	49/Male	Screen	40.0	75.0	%	70.9	N
					Week 4	40.0	75.0	%	59.6	N
					Week 8	40.0	75.0	%	78.9	H
					Wk 32/Final Visit	40.0	75.0	%	80	H
	Walsh	171063	Placebo	27/Male	Screen	40.0	75.0	%	62.9	N
					Week 4	40.0	75.0	%	54.5	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
Total Neutrophils (%)	Walsh	171063	Placebo	27/Male	Week 8	40.0	75.0	%	39.1	L
					Wk 32/Final Visit	40.0	75.0	%	56.1	N
White Cell Count (K/UL)	Clayton	31020	Placebo	55/Male	Screen	3.8	10.8	K/UL	5.3	N
					Week 4	3.8	10.8	K/UL	3.8	N
					Week 8	3.8	10.8	K/UL	4.8	N
					Wk 32/Final Visit	3.8	10.8	K/UL	3.7	L
	Croft	231002	RBX	40/Female	Screen	3.8	10.8	K/UL	7.5	N
					Unscheduled	3.8	10.8	K/UL	14.8	H
	Delgado	41093	RBX	56/Female	Screen	3.8	10.8	K/UL	9.0	N
					Week 4	3.8	10.8	K/UL	9.5	N
					Week 8	3.8	10.8	K/UL	8.6	N
					Wk 32/Final Visit	3.8	10.8	K/UL	11.0	H
	DuBoff	311018	RBX	31/Female	Screen	3.8	10.8	K/UL	4.3	N
					Week 4	3.8	10.8	K/UL	3.6	L
					Week 8	3.8	10.8	K/UL	4.7	N
	Dunner	211040	RBX	53/Female	Screen	3.8	10.8	K/UL	9.9	N
					Week 4	3.8	10.8	K/UL	10.0	N
					Week 8	3.8	10.8	K/UL	13.1	H
					Wk 32/Final Visit	3.8	10.8	K/UL	11.6	H

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
White Cell Count (K/UL)	Helfing	81004	Placebo	43/Female	Screen	3.8	10.8	K/UL	5.1	N
					Week 4	3.8	10.8	K/UL	3.7	L
					Week 8	3.8	10.8	K/UL	5.0	N
					Wk 32/Final Visit	3.8	10.8	K/UL	4.8	N
	Lydiard	221130	RBX	51/Female	Screen	3.8	10.8	K/UL	3.9	N
					Week 4	3.8	10.8	K/UL	3.7	L
	Munjack	131012	Placebo	42/Female	Screen	3.8	10.8	K/UL	9.4	N
					Week 4	3.8	10.8	K/UL	9.9	N
					Week 8	3.8	10.8	K/UL	8.2	N
					Wk 32/Final Visit	3.8	10.8	K/UL	11.4	H
	Nelson	141041	RBX	55/Female	Screen	3.8	10.8	K/UL	4.8	N
					Week 4	3.8	10.8	K/UL	3.9	N
					Week 8	3.8	10.8	K/UL	3.6	L
	Rapaport	151095	RBX	49/Male	Screen	3.8	10.8	K/UL	6.4	N
					Week 4	3.8	10.8	K/UL	5.8	N
					Week 8	3.8	10.8	K/UL	10.0	N
					Wk 32/Final Visit	3.8	10.8	K/UL	11.9	H
		151099	Placebo	52/Female	Screen	3.8	10.8	K/UL	4.0	N
					Week 4	3.8	10.8	K/UL	3.3	L
					Week 8	3.8	10.8	K/UL	5.3	N

Table LAB14

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Hematology Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range High	Unit	Assay Value	Assay-Flag
White Cell Count (K/UL)	Rapaport	151099	Placebo	52/Female	Wk 32/Final Visit	3.8	10.8	K/UL	4.3	N
		151153	RBX	44/Male	Screen	3.8	10.8	K/UL	2.9	L
					Week 8	3.8	10.8	K/UL	3.3	L
	Smith	281101	RBX	40/Female	Screen	3.8	10.8	K/UL	5.1	N
					Week 4	3.8	10.8	K/UL	3.8	N
					Week 8	3.8	10.8	K/UL	3.6	L
	Zajecka	201092	RBX	41/Female	Screen	3.8	10.8	K/UL	2.7	L
					Week 8	3.8	10.8	K/UL	3.6	L
					Unscheduled	3.8	10.8	K/UL	3.5	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
ALAT (SGPT) (U/L)	Croft	231002	RBX	40/Female	Screen	0	48	U/L	22	N
					Unscheduled	0	48	U/L	87	H
	Dunner	211145	RBX	41/Male	Screen	0	48	U/L	78	H
					Week 8	0	48	U/L	88	H
	Helfing	81052	RBX	39/Female	Screen	0	48	U/L	70	H
					Week 8	0	48	U/L	56	H
	Munjack	131126	RBX	45/Male	Screen	0	48	U/L	29	N
					Week 4	0	48	U/L	28	N
					Week 8	0	48	U/L	71	H
	Rapaport	151038	Placebo	52/Male	Screen	0	48	U/L	59	H
					Week 4	0	48	U/L	60	H
					Week 8	0	48	U/L	68	H
					Wk 32/Final Visit	0	48	U/L	52	H
					Unscheduled	0	48	U/L	78	H
						0	48	U/L	49	H
						0	48	U/L	57	H
						0	48	U/L	64	H
						0	48	U/L	60	H
		151095	RBX	49/Male	Screen	0	48	U/L	36	N
					Week 4	0	48	U/L	50	H
					Week 8	0	48	U/L	41	N

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
ALAT (SGPT) (U/L)	Rapaport	151095	RBX	49/Male	Wk 32/Final Visit	0	48	U/L	32	N
	Thase	181106	RBX	28/Male	Screen	0	48	U/L	44	N
					Unscheduled	0	48	U/L	77	H
		181135	RBX	31/Female	Screen	0	48	U/L	52	H
					Week 4	0	48	U/L	61	H
					Week 8	0	48	U/L	92	H
					Unscheduled	0	48	U/L	53	H
	Walsh	171063	Placebo	27/Male	Screen	0	48	U/L	29	N
					Week 4	0	48	U/L	35	N
					Week 8	0	48	U/L	24	N
					Wk 32/Final Visit	0	48	U/L	53	H
	Zajecka	201068	Placebo	37/Female	Screen	0	48	U/L	122	H
					Week 4	0	48	U/L	93	H
					Week 8	0	48	U/L	65	H
					Wk 32/Final Visit	0	48	U/L	53	H
					Unscheduled	0	48	U/L	65	H
						0	48	U/L	124	H
						0	48	U/L	80	H
						0	48	U/L	170	H
						0	48	U/L	199	H
						0	48	U/L	223	H
						0	48	U/L	158	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
ALAT (SGPT) (U/L)	Zajecka	201068	Placebo	37/Female	Unscheduled	0	48	U/L	59	H
ASAT (SGOT) (U/L)	Croft	231119	RBX	56/Female	Screen	0	42	U/L	23	N
					Week 4	0	42	U/L	64	H
					Week 8	0	42	U/L	24	N
					Wk 32/Final Visit	0	42	U/L	25	N
	Dunner	211145	RBX	41/Male	Screen	0	42	U/L	62	H
					Week 8	0	42	U/L	60	H
	Rapaport	151085	RBX	50/Female	Screen	0	42	U/L	20	N
					Week 8	0	42	U/L	50	H
	Thase	181106	RBX	28/Male	Screen	0	42	U/L	27	N
					Unscheduled	0	42	U/L	54	H
		181135	RBX	31/Female	Screen	0	42	U/L	43	H
					Week 4	0	42	U/L	47	H
					Week 8	0	42	U/L	135	H
					Unscheduled	0	42	U/L	45	H
	Zajecka	201068	Placebo	37/Female	Screen	0	42	U/L	58	H
					Week 4	0	42	U/L	36	N
					Week 8	0	42	U/L	30	N
					Wk 32/Final Visit	0	42	U/L	28	N
					Unscheduled	0	42	U/L	35	N

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
ASAT (SGOT) (U/L)	Zajecka	201068	Placebo	37/Female	Unscheduled	0	42	U/L	44	H
						0	42	U/L	37	N
						0	42	U/L	33	N
						0	42	U/L	53	H
						0	42	U/L	74	H
						0	42	U/L	84	H
						0	42	U/L	67	H
Alkaline Phosphase (U/L)	Amsterdam	11066	RBX	56/Male	Screen	20	125	U/L	108	N
					Week 4	20	125	U/L	127	H
					Week 8	20	125	U/L	103	N
					Wk 32/Final Visit	20	125	U/L	102	N
	Croft	231002	RBX	40/Female	Screen	20	125	U/L	63	N
					Unscheduled	20	125	U/L	220	H
	Dunner	211040	RBX	53/Female	Screen	20	125	U/L	142	H
					Week 4	20	125	U/L	144	H
					Week 8	20	125	U/L	141	H
					Wk 32/Final Visit	20	125	U/L	150	H
	McGrath	111058	RBX	20/Female	Screen	20	125	U/L	132	H
					Week 4	20	125	U/L	126	H
					Week 8	20	125	U/L	121	N

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Alkaline Phosphase (U/L)	Munjack	131125	Placebo	34/Female	Screen	20	125	U/L	126	H
					Week 4	20	125	U/L	131	H
					Week 8	20	125	U/L	108	N
					Wk 32/Final Visit	20	125	U/L	105	N
	Oldroyd	321055	RBX	38/Male	Screen	20	125	U/L	97	N
					Week 4	20	125	U/L	129	H
	Smith	281107	RBX	61/Female	Screen	20	125	U/L	195	H
					Week 4	20	125	U/L	184	H
					Week 8	20	125	U/L	188	H
Bilirubin, Total (MG/DL)	Croft	231079	RBX	65/Male	Screen	0.0	1.3	MG/DL	0.7	N
					Week 4	0.0	1.3	MG/DL	0.6	N
					Week 8	0.0	1.3	MG/DL	3.1	H
					Unscheduled	0.0	1.3	MG/DL	0.3	N
	Munjack	131011	Placebo	56/Male	Screen	0.0	1.3	MG/DL	1.0	N
					Week 4	0.0	1.3	MG/DL	0.8	N
					Week 8	0.0	1.3	MG/DL	0.7	N
					Wk 32/Final Visit	0.0	1.3	MG/DL	1.5	H
	Walsh	171016	RBX	37/Male	Screen	0.0	1.3	MG/DL	1.4	H
					Week 4	0.0	1.3	MG/DL	2.2	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
CO2 Content (MEQ/L)	Amsterdam	11065	RBX	59/Male	Screen	20	32	MEQ/L	26	N
					Week 4	20	32	MEQ/L	33	H
	Barbee	21053	RBX	30/Male	Screen	20	32	MEQ/L	25	N
					Week 4	20	32	MEQ/L	18	L
					Week 8	20	32	MEQ/L	24	N
	Ferguson	241031	RBX	61/Male	Screen	20	32	MEQ/L	25	N
					Week 8	20	32	MEQ/L	19	L
	Halbreich	71077	RBX	56/Female	Screen	20	32	MEQ/L	26	N
					Week 4	20	32	MEQ/L	34	H
	Liebowitz	91098	RBX	23/Female	Screen	20	32	MEQ/L	27	N
					Week 8	20	32	MEQ/L	19	L
	Munjack	131072	RBX	58/Male	Screen	20	32	MEQ/L	31	N
					Week 4	20	32	MEQ/L	30	N
					Week 8	20	32	MEQ/L	34	H
	Rapaport	151100	RBX	42/Female	Screen	20	32	MEQ/L	33	H
					Week 4	20	32	MEQ/L	33	H
					Week 8	20	32	MEQ/L	30	N
Chloride (MEQ/L)	Barbee	21053	RBX	30/Male	Screen	95	108	MEQ/L	107	N
					Week 4	95	108	MEQ/L	111	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Chloride (MEQ/L)	Barbee	21053	RBX	30/Male	Week 8	95	108	MEQ/L	106	N
	Clayton	31048	Placebo	46/Female	Screen	95	108	MEQ/L	103	N
					Week 4	95	108	MEQ/L	107	N
					Week 8	95	108	MEQ/L	104	N
					Wk 32/Final Visit	95	108	MEQ/L	110	H
	DuBoff	311115	Placebo	30/Female	Screen	95	108	MEQ/L	107	N
					Week 4	95	108	MEQ/L	102	N
					Week 8	95	108	MEQ/L	107	N
					Wk 32/Final Visit	95	108	MEQ/L	109	H
	Dunner	211147	RBX	37/Female	Screen	95	108	MEQ/L	107	N
					Week 8	95	108	MEQ/L	109	H
	Helfing	81004	Placebo	43/Female	Screen	95	108	MEQ/L	108	N
					Week 4	95	108	MEQ/L	113	H
					Week 8	95	108	MEQ/L	108	N
					Wk 32/Final Visit	95	108	MEQ/L	108	N
	Londborg	101043	RBX	31/Female	Screen	95	108	MEQ/L	104	N
					Week 4	95	108	MEQ/L	106	N
					Week 8	95	108	MEQ/L	107	N
					Wk 32/Final Visit	95	108	MEQ/L	109	H
	Rapaport	151038	Placebo	52/Male	Screen	95	108	MEQ/L	106	N

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Chloride (MEQ/L)	Rapaport	151038	Placebo	52/Male	Week 4	95	108	MEQ/L	104	N
					Week 8	95	108	MEQ/L	107	N
					Wk 32/Final Visit	95	108	MEQ/L	107	N
					Unscheduled	95	108	MEQ/L	109	H
						95	108	MEQ/L	106	N
						95	108	MEQ/L	107	N
						95	108	MEQ/L	108	N
						95	108	MEQ/L	104	N
	Smith	281101	RBX	40/Female	Screen	95	108	MEQ/L	105	N
					Week 4	95	108	MEQ/L	107	N
					Week 8	95	108	MEQ/L	109	H
		281102	Placebo	44/Female	Screen	95	108	MEQ/L	104	N
					Week 4	95	108	MEQ/L	107	N
					Week 8	95	108	MEQ/L	109	H
					Wk 32/Final Visit	95	108	MEQ/L	103	N
	Thase	181083	RBX	58/Male	Screen	95	108	MEQ/L	104	N
					Week 4	95	108	MEQ/L	108	N
					Week 8	95	108	MEQ/L	103	N
					Wk 32/Final Visit	95	108	MEQ/L	111	H
Creatinine (MG/DL)	Clayton	31048	Placebo	46/Female	Screen	0.5	1.4	MG/DL	0.8	N
					Week 4	0.5	1.4	MG/DL	0.9	N
					Week 8	0.5	1.4	MG/DL	0.4	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Creatinine (MG/DL)	Clayton	31048	Placebo	46/Female	Wk 32/Final Visit	0.5	1.4	MG/DL	0.8	N
	Helfing	81075	RBX	37/Female	Screen	0.5	1.4	MG/DL	0.6	N
					Week 4	0.5	1.4	MG/DL	0.6	N
					Wk 32/Final Visit	0.5	1.4	MG/DL	0.6	N
					Unscheduled	0.5	1.4	MG/DL	0.4	L
	Smith	281101	RBX	40/Female	Screen	0.5	1.4	MG/DL	0.7	N
					Week 4	0.5	1.4	MG/DL	0.6	N
					Week 8	0.5	1.4	MG/DL	0.4	L
		281107	RBX	61/Female	Screen	0.5	1.4	MG/DL	0.6	N
					Week 4	0.5	1.4	MG/DL	0.4	L
					Week 8	0.5	1.4	MG/DL	0.7	N
		281108	Placebo	53/Female	Screen	0.5	1.4	MG/DL	0.5	N
					Week 4	0.5	1.4	MG/DL	0.4	L
					Week 8	0.5	1.4	MG/DL	0.5	N
					Wk 32/Final Visit	0.5	1.4	MG/DL	0.4	L
Glucose (MG/DL)	Amsterdam	11133	RBX	41/Male	Screen	70	115	MG/DL	120	H
					Week 4	70	115	MG/DL	153	H
					Week 8	70	115	MG/DL	164	H
		11167	RBX	53/Female	Screen	70	125	MG/DL	60	L
					Week 4	70	125	MG/DL	163	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Glucose (MG/DL)	Amsterdam	11167	RBX	53/Female	Week 8	70	125	MG/DL	74	N
	Croft	231001	RBX	50/Female	Screen	70	125	MG/DL	87	N
					Week 4	70	125	MG/DL	90	N
					Week 8	70	125	MG/DL	88	N
					Wk 32/Final Visit	70	125	MG/DL	<20	L
					Unscheduled	70	125	MG/DL	81	N
	Delgado	41094	RBX	64/Female	Screen	70	125	MG/DL	71	N
					Week 4	70	125	MG/DL	63	L
					Week 8	70	125	MG/DL	71	N
					Wk 32/Final Visit	70	125	MG/DL	87	N
	DuBoff	311017	RBX	54/Male	Screen	70	125	MG/DL	97	N
					Week 4	70	125	MG/DL	131	H
					Week 8	70	125	MG/DL	105	N
					Wk 32/Final Visit	70	125	MG/DL	116	N
	Dunner	211040	RBX	53/Female	Screen	70	125	MG/DL	109	N
					Week 4	70	125	MG/DL	107	N
					Week 8	70	125	MG/DL	67	L
					Wk 32/Final Visit	70	125	MG/DL	92	N
		211145	RBX	41/Male	Screen	70	115	MG/DL	166	H
					Week 8	70	115	MG/DL	173	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Glucose (MG/DL)	Dunner	211147	RBX	37/Female	Screen	70	115	MG/DL	124	H
					Week 8	70	115	MG/DL	62	L
	Fava	51113	RBX	55/Female	Screen	70	125	MG/DL	87	N
					Week 4	70	125	MG/DL	79	N
					Week 8	70	125	MG/DL	69	L
	Helfing	81052	RBX	39/Female	Screen	70	115	MG/DL	103	N
					Week 8	70	115	MG/DL	141	H
		81075	RBX	37/Female	Screen	70	115	MG/DL	95	N
					Week 4	70	115	MG/DL	99	N
					Wk 32/Final Visit	70	115	MG/DL	123	H
					Unscheduled	70	115	MG/DL	136	H
		81076	RBX	23/Female	Screen	70	115	MG/DL	89	N
					Week 4	70	115	MG/DL	114	N
					Week 8	70	115	MG/DL	107	N
					Wk 32/Final Visit	70	115	MG/DL	147	H
	Liebowitz	91137	RBX	40/Male	Screen	70	115	MG/DL	90	N
					Week 4	70	115	MG/DL	118	H
					Week 8	70	115	MG/DL	91	N
	Londborg	101009	RBX	36/Female	Screen	70	115	MG/DL	73	N
					Week 8	70	115	MG/DL	68	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Glucose (MG/DL)	Londborg	101043	RBX	31/Female	Screen	70	115	MG/DL	87	N
					Week 4	70	115	MG/DL	67	L
					Week 8	70	115	MG/DL	66	L
					Wk 32/Final Visit	70	115	MG/DL	54	L
	Lydiard	221033	RBX	44/Male	Screen	70	115	MG/DL	60	L
					Week 4	70	115	MG/DL	96	N
					Week 8	70	115	MG/DL	60	L
					Wk 32/Final Visit	70	115	MG/DL	76	N
	Rapaport	151099	Placebo	52/Female	Screen	70	125	MG/DL	85	N
					Week 4	70	125	MG/DL	130	H
					Week 8	70	125	MG/DL	98	N
					Wk 32/Final Visit	70	125	MG/DL	102	N
		151100	RBX	42/Female	Screen	70	115	MG/DL	99	N
					Week 4	70	115	MG/DL	97	N
					Week 8	70	115	MG/DL	137	H
		151117	RBX	49/Female	Screen	70	115	MG/DL	115	N
					Week 4	70	115	MG/DL	103	N
					Week 8	70	115	MG/DL	123	H
		151153	RBX	44/Male	Screen	70	115	MG/DL	103	N
					Week 8	70	115	MG/DL	130	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Glucose (MG/DL)	Smith	281101	RBX	40/Female	Screen	70	115	MG/DL	84	N
					Week 4	70	115	MG/DL	72	N
					Week 8	70	115	MG/DL	68	L
	Thase	181136	RBX	55/Female	Screen	70	125	MG/DL	101	N
					Week 4	70	125	MG/DL	194	H
					Week 8	70	125	MG/DL	112	N
	Trivedi	191014	RBX	47/Male	Screen	70	115	MG/DL	126	H
					Week 8	70	115	MG/DL	131	H
	Zajecka	201123	RBX	43/Female	Screen	70	115	MG/DL	70	N
					Week 4	70	115	MG/DL	76	N
					Week 8	70	115	MG/DL	59	L
Potassium (MEQ/L)	Amsterdam	11167	RBX	53/Female	Screen	3.5	5.3	MEQ/L	4.6	N
					Week 4	3.5	5.3	MEQ/L	5.4	H
					Week 8	3.5	5.3	MEQ/L	4.6	N
	Helfing	81051	RBX	37/Female	Screen	3.5	5.3	MEQ/L	3.6	N
					Week 4	3.5	5.3	MEQ/L	3.2	L
	Liebowitz	91097	RBX	38/Female	Screen	3.5	5.3	MEQ/L	4.3	N
					Week 4	3.5	5.3	MEQ/L	4.1	N
					Week 8	3.5	5.3	MEQ/L	3.4	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Potassium (MEQ/L)	Lydiard	221130	RBX	51/Female	Screen	3.5	5.3	MEQ/L	5.0	N
					Week 4	3.5	5.3	MEQ/L	5.8	H
	Rapaport	151038	Placebo	52/Male	Screen	3.5	5.3	MEQ/L	4.7	N
					Week 4	3.5	5.3	MEQ/L	5.0	N
					Week 8	3.5	5.3	MEQ/L	4.9	N
					Wk 32/Final Visit	3.5	5.3	MEQ/L	5.2	N
					Unscheduled	3.5	5.3	MEQ/L	5.5	H
						3.5	5.3	MEQ/L	4.9	N
						3.5	5.3	MEQ/L	4.5	N
						3.5	5.3	MEQ/L	5.0	N
						3.5	5.3	MEQ/L	4.9	N
		151153	RBX	44/Male	Screen	3.5	5.3	MEQ/L	4.5	N
					Week 8	3.5	5.3	MEQ/L	5.4	H
	Smith	281108	Placebo	53/Female	Screen	3.5	5.3	MEQ/L	3.8	N
					Week 4	3.5	5.3	MEQ/L	3.7	N
					Week 8	3.5	5.3	MEQ/L	3.2	L
					Wk 32/Final Visit	3.5	5.3	MEQ/L	3.6	N
Reticulocyte Count (%)	Amsterdam	11133	RBX	41/Male	Screen	0.8	3.5	%	2.6	N
					Week 4	0.8	3.5	%	5.9	H
					Week 8	0.8	3.5	%	1.0	N
		11134	RBX	49/Male	Screen	0.8	3.5	%	4.2	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Reticulocyte Count (%)	Amsterdam	11134	RBX	49/Male	Week 4	0.8	3.5	%	5.4	H
					Week 8	0.8	3.5	%	2.2	N
	Croft	231120	RBX	54/Female	Screen	0.8	3.5	%	1.7	N
					Week 4	0.8	3.5	%	0.6	L
					Week 8	0.8	3.5	%	1.1	N
					Wk 32/Final Visit	0.8	3.5	%	1.0	N
	Hoopes	271022	RBX	42/Female	Screen	0.8	3.5	%	1.7	N
					Week 4	0.8	3.5	%	1.7	N
					Week 8	0.8	3.5	%	0.5	L
					Wk 32/Final Visit	0.8	3.5	%	1.9	N
	Munjack	131143	RBX	39/Female	Screen	0.8	3.5	%	1.6	N
					Week 4	0.8	3.5	%	0.7	L
					Week 8	0.8	3.5	%	1.0	N
	Smith	281108	Placebo	53/Female	Screen	0.8	3.5	%	3.7	H
					Week 4	0.8	3.5	%	3.7	H
					Week 8	0.8	3.5	%	3.8	H
					Wk 32/Final Visit	0.8	3.5	%	4.3	H
	Thase	181136	RBX	55/Female	Week 4	0.8	3.5	%	2.8	N
					Week 8	0.8	3.5	%	4.1	H
					Unscheduled	0.8	3.5	%	4.3	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Reticulocyte Count (%)	Walsh	171027	RBX	52/Female	Screen	0.8	3.5	%	1.4	N
					Week 4	0.8	3.5	%	0.7	L
					Week 8	0.8	3.5	%	0.8	N
		171028	RBX	45/Female	Screen	0.8	3.5	%	0.9	N
					Week 8	0.8	3.5	%	0.5	L
Sodium (MEQ/L)	Barbee	21053	RBX	30/Male	Screen	135	146	MEQ/L	145	N
					Week 4	135	146	MEQ/L	152	H
					Week 8	135	146	MEQ/L	141	N
	Dunner	211147	RBX	37/Female	Screen	135	146	MEQ/L	136	N
					Week 8	135	146	MEQ/L	147	H
	Gilmer	61081	RBX	45/Female	Screen	135	146	MEQ/L	136	N
					Week 8	135	146	MEQ/L	134	L
	Helfing	81003	Placebo	65/Female	Screen	135	146	MEQ/L	134	L
					Week 4	135	146	MEQ/L	136	N
					Week 8	135	146	MEQ/L	134	L
					Unscheduled	135	146	MEQ/L	137	N
	McGrath	111171	RBX	50/Male	Screen	135	146	MEQ/L	149	H
					Week 4	135	146	MEQ/L	140	N
					Week 8	135	146	MEQ/L	145	N
					Unscheduled	135	146	MEQ/L	148	H

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Sodium (MEQ/L)	McGrath	111171	RBX	50/Male	Unscheduled	135	146	MEQ/L	146	N
	Thase	181136	RBX	55/Female	Screen	135	146	MEQ/L	140	N
					Week 4	135	146	MEQ/L	134	L
					Week 8	135	146	MEQ/L	143	N
Urea Nitrogen (MG/DL)	Amsterdam	11167	RBX	53/Female	Screen	7	25	MG/DL	22	N
					Week 4	7	25	MG/DL	27	H
					Week 8	7	25	MG/DL	28	H
	Dunner	211147	RBX	37/Female	Screen	7	25	MG/DL	9	N
					Week 8	7	25	MG/DL	6	L
	Fava	51113	RBX	55/Female	Screen	7	25	MG/DL	13	N
					Week 4	7	25	MG/DL	29	H
					Week 8	7	25	MG/DL	18	N
	McGrath	111058	RBX	20/Female	Screen	7	25	MG/DL	7	N
					Week 4	7	25	MG/DL	8	N
					Week 8	7	25	MG/DL	6	L
	Munjack	131012	Placebo	42/Female	Screen	7	25	MG/DL	6	L
					Week 4	7	25	MG/DL	8	N
					Week 8	7	25	MG/DL	9	N
					Wk 32/Final Visit	7	25	MG/DL	5	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Uric Acid (MG/DL)	Clayton	31020	Placebo	55/Male	Screen	4.0	8.5	MG/DL	4.4	N
					Week 4	4.0	8.5	MG/DL	3.4	L
					Week 8	4.0	8.5	MG/DL	4.1	N
					Wk 32/Final Visit	4.0	8.5	MG/DL	4.1	N
	Croft	231120	RBX	54/Female	Screen	2.5	7.5	MG/DL	2.7	N
					Week 4	2.5	7.5	MG/DL	2.2	L
					Week 8	2.5	7.5	MG/DL	3.6	N
					Wk 32/Final Visit	2.5	7.5	MG/DL	3.9	N
	Dunner	211146	RBX	57/Male	Screen	4.0	8.5	MG/DL	3.6	L
					Week 4	4.0	8.5	MG/DL	3.8	L
					Week 8	4.0	8.5	MG/DL	4.9	N
	Fava	51142	RBX	44/Female	Screen	2.5	7.5	MG/DL	3.4	N
					Week 4	2.5	7.5	MG/DL	2.0	L
					Week 8	2.5	7.5	MG/DL	3.5	N
	Ferguson	241073	RBX	26/Female	Screen	2.5	7.5	MG/DL	2.9	N
					Week 4	2.5	7.5	MG/DL	2.3	L
					Week 8	2.5	7.5	MG/DL	2.7	N
	Helfing	81003	Placebo	65/Female	Screen	2.5	7.5	MG/DL	3.2	N
					Week 4	2.5	7.5	MG/DL	2.8	N
					Week 8	2.5	7.5	MG/DL	3.0	N
					Unscheduled	2.5	7.5	MG/DL	2.3	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Uric Acid (MG/DL)	Helfing	81004	Placebo	43/Female	Screen	2.5	7.5	MG/DL	2.0	L
					Week 4	2.5	7.5	MG/DL	2.4	L
					Week 8	2.5	7.5	MG/DL	3.1	N
					Wk 32/Final Visit	2.5	7.5	MG/DL	2.3	L
		81103	Placebo	48/Female	Screen	2.5	7.5	MG/DL	3.2	N
					Week 4	2.5	7.5	MG/DL	2.1	L
					Week 8	2.5	7.5	MG/DL	2.5	N
					Wk 32/Final Visit	2.5	7.5	MG/DL	1.7	L
	Hoopes	271021	RBX	29/Male	Screen	4.0	8.5	MG/DL	3.8	L
					Week 4	4.0	8.5	MG/DL	4.4	N
					Week 8	4.0	8.5	MG/DL	3.7	L
	Londborg	101043	RBX	31/Female	Screen	2.5	7.5	MG/DL	2.7	N
					Week 4	2.5	7.5	MG/DL	3.2	N
					Week 8	2.5	7.5	MG/DL	2.1	L
					Wk 32/Final Visit	2.5	7.5	MG/DL	2.9	N
		101044	Placebo	41/Female	Screen	2.5	7.5	MG/DL	2.3	L
					Week 4	2.5	7.5	MG/DL	3.3	N
					Week 8	2.5	7.5	MG/DL	3.9	N
					Wk 32/Final Visit	2.5	7.5	MG/DL	1.8	L
	Lydiard	221033	RBX	44/Male	Screen	4.0	8.5	MG/DL	3.8	L
					Week 4	4.0	8.5	MG/DL	3.5	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Uric Acid (MG/DL)	Lydiard	221033	RBX	44/Male	Week 8	4.0	8.5	MG/DL	4.1	N
					Wk 32/Final Visit	4.0	8.5	MG/DL	4.3	N
		221129	RBX	51/Male	Screen	4.0	8.5	MG/DL	4.2	N
					Week 8	4.0	8.5	MG/DL	3.6	L
	Munjack	131012	Placebo	42/Female	Screen	2.5	7.5	MG/DL	2.4	L
					Week 4	2.5	7.5	MG/DL	2.6	N
					Week 8	2.5	7.5	MG/DL	2.3	L
					Wk 32/Final Visit	2.5	7.5	MG/DL	2.3	L
	Oldroyd	321087	RBX	55/Male	Screen	4.0	8.5	MG/DL	4.4	N
					Week 4	4.0	8.5	MG/DL	4.5	N
					Week 8	4.0	8.5	MG/DL	3.9	L
					Wk 32/Final Visit	4.0	8.5	MG/DL	5.0	N
	Rapaport	151038	Placebo	52/Male	Screen	4.0	8.5	MG/DL	7.5	N
					Week 4	4.0	8.5	MG/DL	7.0	N
					Week 8	4.0	8.5	MG/DL	6.7	N
					Wk 32/Final Visit	4.0	8.5	MG/DL	9.9	H
					Unscheduled	4.0	8.5	MG/DL	6.7	N
						4.0	8.5	MG/DL	6.8	N
						4.0	8.5	MG/DL	7.5	N
						4.0	8.5	MG/DL	7.6	N
						4.0	8.5	MG/DL	6.7	N

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Uric Acid (MG/DL)	Rapaport	151099	Placebo	52/Female	Screen	2.5	7.5	MG/DL	1.6	L
					Week 4	2.5	7.5	MG/DL	2.5	N
					Week 8	2.5	7.5	MG/DL	1.9	L
					Wk 32/Final Visit	2.5	7.5	MG/DL	3.0	N
	Thase	181106	RBX	28/Male	Screen	4.0	8.5	MG/DL	4.0	N
					Unscheduled	4.0	8.5	MG/DL	3.4	L
	Walsh	171015	Placebo	45/Female	Screen	2.5	7.5	MG/DL	3.6	N
					Week 4	2.5	7.5	MG/DL	4.5	N
					Week 8	2.5	7.5	MG/DL	2.4	L
					Wk 32/Final Visit	2.5	7.5	MG/DL	2.7	N
	Zajecka	201068	Placebo	37/Female	Screen	2.5	7.5	MG/DL	3.3	N
					Week 4	2.5	7.5	MG/DL	2.1	L
					Week 8	2.5	7.5	MG/DL	2.7	N
					Wk 32/Final Visit	2.5	7.5	MG/DL	3.1	N
					Unscheduled	2.5	7.5	MG/DL	2.5	N
						2.5	7.5	MG/DL	2.9	N
						2.5	7.5	MG/DL	2.1	L
						2.5	7.5	MG/DL	1.5	L
						2.5	7.5	MG/DL	2.5	N
						2.5	7.5	MG/DL	2.7	N
						2.5	7.5	MG/DL	3.4	N
						2.5	7.5	MG/DL	2.3	L

Table LAB15

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Chemistry Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmt in Blinded Phase	Age/Sex	Study Period	Normal Range Low	Normal Range Hi	Unit	Assay Value	Assay-Flag
Uric Acid (MG/DL)	Zajecka	201092	RBX	41/Female	Screen	2.5	7.5	MG/DL	0.8	L
					Week 8	2.5	7.5	MG/DL	0.6	L
					Unscheduled	2.5	7.5	MG/DL	0.9	L

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Delgado	41069	RBX	41/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
		41070	RBX	46/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
		41093	RBX	56/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		CLOUDY	A
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
					Unscheduled	CLEAR	CLEAR		CLEAR	N
						CLEAR	CLEAR		CLEAR	N
	DuBoff	311115	Placebo	30/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		HAZY	A
	Dunner	211040	RBX	53/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Dunner	211109	RBX	43/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
		211110	Placebo	54/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
		211146	RBX	57/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
	Fava	51141	RBX	30/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		HAZY	A
	Ferguson	241073	RBX	26/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		TURBID	A
		241074	RBX	21/Female	Screen	CLEAR	CLEAR		HAZY	A
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		CLOUDY	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Helfing	81004	Placebo	43/Female	Screen	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
					Unscheduled	CLEAR	CLEAR		HAZY	A
		81076	RBX	23/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		TURBID	A
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
	Hoopes	271021	RBX	29/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
		271045	RBX	18/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
	Liebowitz	91005	RBX	54/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		CLOUDY	A
		91035	RBX	62/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		CLOUDY	A
		91097	RBX	38/Female	Screen	CLEAR	CLEAR		CLEAR	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Liebowitz	91097	RBX	38/Female	Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
		91138	RBX	45/Female	Screen	CLEAR	CLEAR		HAZY	A
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
	Londborg	101009	RBX	36/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
	Lydiard	221130	RBX	51/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Unscheduled	CLEAR	CLEAR		CLEAR	N
	Munjack	131072	RBX	58/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
		131125	Placebo	34/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
					Wk 32/Final Visit	CLEAR	CLEAR		HAZY	A
		131126	RBX	45/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
					Unscheduled	CLEAR	CLEAR		CLEAR	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Nelson	141041	RBX	55/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
	Oldroyd	321087	RBX	55/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
	Prover	261023	RBX	33/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		HAZY	A
					Week 8	CLEAR	CLEAR		HAZY	A
	Rapaport	151037	Placebo	62/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
		151086	RBX	45/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		TURBID	A
					Week 8	CLEAR	CLEAR		CLEAR	N
		151100	RBX	42/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Week 8	CLEAR	CLEAR		HAZY	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Appearance	Smith	281025	RBX	41/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		TURBID	A
		281101	RBX	40/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		HAZY	A
	Thase	181135	RBX	31/Female	Screen	CLEAR	CLEAR		HAZY	A
					Week 4	CLEAR	CLEAR		CLOUDY	A
					Week 8	CLEAR	CLEAR		CLOUDY	A
	Walsh	171028	RBX	45/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		TURBID	A
		171062	Placebo	52/Female	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		TURBID	A
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		CLEAR	N
	Zajecka	201067	RBX	31/Male	Screen	CLEAR	CLEAR		CLEAR	N
					Week 4	CLEAR	CLEAR		CLEAR	N
					Week 8	CLEAR	CLEAR		CLEAR	N
					Wk 32/Final Visit	CLEAR	CLEAR		HAZY	A
Bilirubin	Londborg	101044	Placebo	41/Female	Screen	0	0		0	N
					Week 4	0	0		0	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Bilirubin	Londborg	101044	Placebo	41/Female	Week 8	0	0		1	A
					Wk 32/Final Visit	0	0		0	N
					Unscheduled	0	0		0	N
Blood (Occult)	Delgado	41069	RBX	41/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		0	N
					Wk 32/Final Visit	0	0		T	A
	Dunner	211147	RBX	37/Female	Screen	0	0		1	A
					Week 8	0	0		T	A
	Fava	51141	RBX	30/Female	Screen	0	0		0	N
					Week 4	0	0		1	A
					Week 8	0	0		T	A
	Liebowitz	91097	RBX	38/Female	Screen	0	0		0	N
					Week 4	0	0		2	A
					Week 8	0	0		0	N
	Londborg	101010	RBX	51/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		3	A
	Rapaport	151086	RBX	45/Female	Screen	0	0		0	N
					Week 4	0	0		3	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Blood (Occult)	Rapaport	151086	RBX	45/Female	Week 8	0	0		0	N
	Smith	281025	RBX	41/Female	Screen	0	0		0	N
					Week 8	0	0		3	A
		281101	RBX	40/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		3	A
	Thase	181135	RBX	31/Female	Screen	0	0		0	N
					Week 4	0	0		2	A
					Week 8	0	0		0	N
	Walsh	171028	RBX	45/Female	Screen	0	0		0	N
					Week 8	0	0		3	A
	Zajecka	201091	RBX	34/Female	Screen	0	0		1	A
					Unscheduled	0	0		T	A
Leukocytes	Amsterdam	11167	RBX	53/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		TRACE	A
	Clayton	31019	RBX	45/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		TRACE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N

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Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Leukocytes	Clayton	31019	RBX	45/Male	Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
	Croft	231120	RBX	54/Female	Screen	NEGATIVE	NEGATIVE		1+	A
					Week 4	NEGATIVE	NEGATIVE		TRACE	A
					Week 8	NEGATIVE	NEGATIVE		1+	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
	Delgado	41069	RBX	41/Female	Screen	NEGATIVE	NEGATIVE		1+	A
					Week 4	NEGATIVE	NEGATIVE		2+	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		41093	RBX	56/Female	Screen	NEGATIVE	NEGATIVE		1+	A
					Week 4	NEGATIVE	NEGATIVE		1+	A
					Week 8	NEGATIVE	NEGATIVE		2+	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		1+	A
					Unscheduled	NEGATIVE	NEGATIVE		NEGATIVE	N
						NEGATIVE	NEGATIVE		NEGATIVE	N
		41094	RBX	64/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		1+	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		1+	A
	Dunner	211109	RBX	43/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Leukocytes	Dunner	211109	RBX	43/Male	Week 8	NEGATIVE	NEGATIVE		1+	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		211147	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		1+	A
	Fava	51141	RBX	30/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		3+	A
					Week 8	NEGATIVE	NEGATIVE		3+	A
	Ferguson	241073	RBX	26/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		1+	A
	Helfing	81075	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		TRACE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
	Liebowitz	91005	RBX	54/Female	Screen	NEGATIVE	NEGATIVE		TRACE	A
					Week 8	NEGATIVE	NEGATIVE		3+	A
		91035	RBX	62/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		2+	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Leukocytes	Liebowitz	91097	RBX	38/Female	Screen	NEGATIVE	NEGATIVE		2+	A
					Week 4	NEGATIVE	NEGATIVE		2+	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
	Lydiard	221130	RBX	51/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		2+	A
					Unscheduled	NEGATIVE	NEGATIVE		NEGATIVE	N
	Nelson	141041	RBX	55/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		2+	A
					Week 8	NEGATIVE	NEGATIVE		TRACE	A
	Prover	261023	RBX	33/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		2+	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
	Rapaport	151038	Placebo	52/Male	Screen	NEGATIVE	NEGATIVE		2+	A
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		TRACE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		1+	A
					Unscheduled	NEGATIVE	NEGATIVE		NEGATIVE	N
		151085	RBX	50/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		TRACE	A
	Smith	281026	RBX	46/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Leukocytes	Smith	281026	RBX	46/Female	Week 4	NEGATIVE	NEGATIVE		TRACE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
	Thase	181105	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		TRACE	A
					Week 4	NEGATIVE	NEGATIVE		1+	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
		181135	RBX	31/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		1+	A
					Week 8	NEGATIVE	NEGATIVE		2+	A
	Walsh	171027	RBX	52/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		TRACE	A
Microscopic Findings Other than Urine RBCs & WBCs	Amsterdam	11066	RBX	56/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		11133	RBX	41/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		11134	RBX	49/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Amsterdam	11134	RBX	49/Male	Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		11159	RBX	48/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		11160	RBX	61/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		11167	RBX	53/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Barbee	21053	RBX	30/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Clayton	31019	RBX	45/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		31020	Placebo	55/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Clayton	31020	Placebo	55/Male	Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		31047	RBX	27/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		31048	Placebo	46/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		31111	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		31112	RBX	44/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Croft	231002	RBX	40/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		231079	RBX	65/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Croft	231079	RBX	65/Male	Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		231080	RBX	55/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		231119	RBX	56/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		231120	RBX	54/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		231139	RBX	36/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Delgado	41069	RBX	41/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A

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Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
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Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Delgado	41070	RBX	46/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		41093	RBX	56/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
						NEGATIVE	NEGATIVE		POSITIVE	A
		41094	RBX	64/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	DuBoff	311017	RBX	54/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		311018	RBX	31/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	DuBoff	311115	Placebo	30/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	Dunner	211039	RBX	53/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		211040	RBX	53/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		211109	RBX	43/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		211110	Placebo	54/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Dunner	211145	RBX	41/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		211146	RBX	57/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		211147	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Fava	51113	RBX	55/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		51141	RBX	30/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		51142	RBX	44/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Ferguson	241031	RBX	61/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Ferguson	241073	RBX	26/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		241074	RBX	21/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Gilmer	61081	RBX	45/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Halbreich	71077	RBX	56/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
	Helfing	81003	Placebo	65/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
						NEGATIVE	NEGATIVE		POSITIVE	A
		81004	Placebo	43/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		81051	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Helfing	81051	RBX	37/Female	Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
		81052	RBX	39/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		81075	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		81076	RBX	23/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		81103	Placebo	48/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	Hoopes	271021	RBX	29/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Hoopes	271022	RBX	42/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		271045	RBX	18/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Liebowitz	91005	RBX	54/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		91006	RBX	44/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		91035	RBX	62/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		91097	RBX	38/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		91137	RBX	40/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Liebowitz	91137	RBX	40/Male	Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
		91138	RBX	45/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Londborg	101009	RBX	36/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		101010	RBX	51/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
		101043	RBX	31/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		101044	Placebo	41/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Lydiard	221033	RBX	44/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		221034	RBX	40/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		221129	RBX	51/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		221130	RBX	51/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
	McGrath	111058	RBX	20/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		111171	RBX	50/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		NEGATIVE	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Moreines	121007	RBX	33/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	Munjack	131011	Placebo	56/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		131012	Placebo	42/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		131071	RBX	25/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
		131072	RBX	58/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		131125	Placebo	34/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Munjack	131126	RBX	45/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		131143	RBX	39/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		131144	RBX	33/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Nelson	141041	RBX	55/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Oldroyd	321055	RBX	38/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
		321056	RBX	44/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		321087	RBX	55/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Oldroyd	321087	RBX	55/Male	Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	Prover	261023	RBX	33/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Rapaport	151037	Placebo	62/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		151038	Placebo	52/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		151085	RBX	50/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		151086	RBX	45/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Rapaport	151095	RBX	49/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		151096	Placebo	60/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		151099	Placebo	52/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		151100	RBX	42/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		151117	RBX	49/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Rapaport	151118	RBX	47/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		151153	RBX	44/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Smith	281025	RBX	41/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		281026	RBX	46/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		281101	RBX	40/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		281102	Placebo	44/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		281107	RBX	61/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Smith	281107	RBX	61/Female	Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		281108	Placebo	53/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
	Thase	181083	RBX	58/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		181084	Placebo	32/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		181105	RBX	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		181106	RBX	28/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Thase	181135	RBX	31/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		181136	RBX	55/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Trivedi	191013	RBX	36/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		191014	RBX	47/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Walsh	171015	Placebo	45/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		171016	RBX	37/Male	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
		171027	RBX	52/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Walsh	171028	RBX	45/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		171061	RBX	47/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
		171062	Placebo	52/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
		171063	Placebo	27/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		NEGATIVE	N
		171064	RBX	21/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Zajecka	201067	RBX	31/Male	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Microscopic Findings Other than Urine RBCs & WBCs	Zajecka	201068	Placebo	37/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
						NEGATIVE	NEGATIVE		POSITIVE	A
		201091	RBX	34/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		201092	RBX	41/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE		POSITIVE	A
		201123	RBX	43/Female	Screen	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 4	NEGATIVE	NEGATIVE		POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
Nitrite	Liebowitz	91035	RBX	62/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A
	Rapaport	151100	RBX	42/Female	Screen	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 4	NEGATIVE	NEGATIVE		NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE		POSITIVE	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
PH (Urine Reaction)	Delgado	41069	RBX	41/Female	Screen	4.6	8.0		7.5	N
					Week 4	4.6	8.0		7.5	N
					Week 8	4.6	8.0		8.5	H
					Wk 32/Final Visit	4.6	8.0		8.0	N
		41070	RBX	46/Female	Screen	4.6	8.0		7.5	N
					Week 4	4.6	8.0		8.5	H
					Week 8	4.6	8.0		7.5	N
		41094	RBX	64/Female	Screen	4.6	8.0		7.0	N
					Week 4	4.6	8.0		7.5	N
					Week 8	4.6	8.0		8.5	H
					Wk 32/Final Visit	4.6	8.0		8.5	H
	Fava	51141	RBX	30/Female	Screen	4.6	8.0		8.5	H
					Week 4	4.6	8.0		7.5	N
					Week 8	4.6	8.0		8.5	H
	Helfing	81003	Placebo	65/Female	Screen	4.6	8.0		7.5	N
					Unscheduled	4.6	8.0		6.0	N
						4.6	8.0		8.5	H
		81103	Placebo	48/Female	Screen	4.6	8.0		8.5	H
					Week 4	4.6	8.0		8.0	N
					Week 8	4.6	8.0		8.5	H
					Wk 32/Final Visit	4.6	8.0		8.0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
PH (Urine Reaction)	Liebowitz	91137	RBX	40/Male	Screen	4.6	8.0		7.0	N
					Week 4	4.6	8.0		6.0	N
					Week 8	4.6	8.0		8.5	H
	McGrath	111058	RBX	20/Female	Screen	4.6	8.0		7.5	N
					Week 4	4.6	8.0		7.5	N
					Week 8	4.6	8.0		8.5	H
	Munjack	131012	Placebo	42/Female	Screen	4.6	8.0		8.0	N
					Week 4	4.6	8.0		8.5	H
					Week 8	4.6	8.0		7.0	N
					Wk 32/Final Visit	4.6	8.0		8.0	N
		131144	RBX	33/Female	Screen	4.6	8.0		8.0	N
					Week 4	4.6	8.0		8.0	N
					Week 8	4.6	8.0		8.5	H
	Oldroyd	321087	RBX	55/Male	Screen	4.6	8.0		7.5	N
					Week 4	4.6	8.0		6.5	N
					Week 8	4.6	8.0		8.5	H
					Wk 32/Final Visit	4.6	8.0		7.5	N
	Walsh	171061	RBX	47/Female	Screen	4.6	8.0		8.0	N
					Week 4	4.6	8.0		8.5	H
					Week 8	4.6	8.0		8.0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
PH (Urine Reaction)	Walsh	171062	Placebo	52/Female	Screen	4.6	8.0		8.5	H
					Week 4	4.6	8.0		6.5	N
					Week 8	4.6	8.0		8.5	H
					Wk 32/Final Visit	4.6	8.0		8.5	H
	Zajecka	201092	RBX	41/Female	Screen	4.6	8.0		7.5	N
					Week 8	4.6	8.0		8.5	H
					Unscheduled	4.6	8.0		8.0	N
		201123	RBX	43/Female	Screen	4.6	8.0		8.0	N
					Week 4	4.6	8.0		8.5	H
					Week 8	4.6	8.0		7.5	N
Protein, Qualitative	Amsterdam	11160	RBX	61/Male	Screen	0	0		0	N
					Week 8	0	0		0	N
					Unscheduled	0	0		1	A
	Barbee	21053	RBX	30/Male	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
	Clayton	31047	RBX	27/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
		31048	Placebo	46/Female	Screen	0	0		0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Protein, Qualitative	Clayton	31048	Placebo	46/Female	Week 4	0	0		0	N
					Week 8	0	0		0	N
					Wk 32/Final Visit	0	0		1	A
	DuBoff	311018	RBX	31/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
		311115	Placebo	30/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
					Wk 32/Final Visit	0	0		0	N
	Dunner	211039	RBX	53/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
		211145	RBX	41/Male	Screen	0	0		1	A
					Week 8	0	0		2	A
	Fava	51141	RBX	30/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
	Halbreich	71077	RBX	56/Female	Screen	0	0		T	A
					Week 4	0	0		T	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Protein, Qualitative	Helfing	81075	RBX	37/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
	Liebowitz	91005	RBX	54/Female	Screen	0	0		0	N
					Week 8	0	0		T	A
		91138	RBX	45/Female	Screen	0	0		T	A
					Week 4	0	0		T	A
					Week 8	0	0		1	A
	Londborg	101009	RBX	36/Female	Screen	0	0		0	N
					Week 8	0	0		1	A
	Oldroyd	321087	RBX	55/Male	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
	Rapaport	151038	Placebo	52/Male	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		T	A
					Unscheduled	0	0		0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Protein, Qualitative	Smith	281025	RBX	41/Female	Screen	0	0		0	N
					Week 8	0	0		T	A
		281108	Placebo	53/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
	Thase	181135	RBX	31/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		T	A
	Walsh	171062	Placebo	52/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
	Zajecka	201068	Placebo	37/Female	Screen	0	0		T	A
					Week 4	0	0		T	A
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
					Unscheduled	0	0		0	N
						0	0		0	N
RBC/HPF	Dunner	211147	RBX	37/Female	Screen	0	3	/HPF	1-3	N
					Week 8	0	3	/HPF	3-5	A

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
RBC/HPF	Fava	51141	RBX	30/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 4	0	3	/HPF	3-5	A
					Week 8	0	3	/HPF	5-10	A
	Rapaport	151086	RBX	45/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 4	0	3	/HPF	15-25	A
					Week 8	0	3	/HPF	NONE SEEN	N
		151099	Placebo	52/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 4	0	3	/HPF	3-5	A
					Week 8	0	3	/HPF	NONE SEEN	N
					Wk 32/Final Visit	0	3	/HPF	NONE SEEN	N
					Unscheduled	0	3	/HPF	NONE SEEN	N
	Smith	281025	RBX	41/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 8	0	3	/HPF	25-50	A
		281101	RBX	40/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 4	0	3	/HPF	NONE SEEN	N
					Week 8	0	3	/HPF	INNUMERABLE	A
	Thase	181135	RBX	31/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 4	0	3	/HPF	10-15	A
					Week 8	0	3	/HPF	NONE SEEN	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
RBC/HPF	Walsh	171028	RBX	45/Female	Screen	0	3	/HPF	NONE SEEN	N
					Week 8	0	3	/HPF	25-50	A
Urine Color	Croft	231002	RBX	40/Female	Screen	YELLOW	YELLOW		YELLOW	N
					Unscheduled	YELLOW	YELLOW		DARK YELLOW	A
	Oldroyd	321087	RBX	55/Male	Screen	YELLOW	YELLOW		YELLOW	N
					Week 4	YELLOW	YELLOW		YELLOW	N
					Week 8	YELLOW	YELLOW		COLORLESS	A
					Wk 32/Final Visit	YELLOW	YELLOW		YELLOW	N
	Rapaport	151086	RBX	45/Female	Screen	YELLOW	YELLOW		YELLOW	N
					Week 4	YELLOW	YELLOW		DARK YELLOW	A
					Week 8	YELLOW	YELLOW		YELLOW	N
	Smith	281025	RBX	41/Female	Screen	YELLOW	YELLOW		YELLOW	N
					Week 8	YELLOW	YELLOW		DARK YELLOW	A
	Walsh	171028	RBX	45/Female	Screen	YELLOW	YELLOW		YELLOW	N
					Week 8	YELLOW	YELLOW		DARK YELLOW	A
Urine Ketones	Clayton	31019	RBX	45/Male	Screen	0	0		0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Urine Ketones	Clayton	31019	RBX	45/Male	Week 4	0	0		0	N
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		T	A
	DuBoff	311018	RBX	31/Female	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
		311115	Placebo	30/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		T	A
					Wk 32/Final Visit	0	0		0	N
	Dunner	211146	RBX	57/Male	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		1	A
	Halbreich	71077	RBX	56/Female	Screen	0	0		1	A
					Week 4	0	0		T	A
	Helfing	81004	Placebo	43/Female	Screen	0	0		1	A
					Week 8	0	0		1	A
					Wk 32/Final Visit	0	0		0	N
					Unscheduled	0	0		0	N
		81052	RBX	39/Female	Screen	0	0		0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
Urine Ketones	Helfing	81052	RBX	39/Female	Week 8	0	0		T	A
	Liebowitz	91137	RBX	40/Male	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
	Lydiard	221130	RBX	51/Female	Screen	0	0		1	A
					Week 4	0	0		0	N
					Unscheduled	0	0		2	A
	McGrath	111171	RBX	50/Male	Screen	0	0		0	N
					Week 4	0	0		T	A
					Week 8	0	0		0	N
					Unscheduled	0	0		0	N
	Munjack	131125	Placebo	34/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		0	N
					Wk 32/Final Visit	0	0		T	A
	Zajecka	201068	Placebo	37/Female	Screen	0	0		0	N
					Week 4	0	0		0	N
					Week 8	0	0		0	N
					Wk 32/Final Visit	0	0		1	A
					Unscheduled	0	0		0	N
						0	0		0	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
WBC/HPF	Delgado	41069	RBX	41/Female	Screen	0	10	/HPF	3-5	N
					Week 4	0	10	/HPF	10-15	A
					Week 8	0	10	/HPF	NONE SEEN	N
					Wk 32/Final Visit	0	10	/HPF	0-1	N
		41093	RBX	56/Female	Screen	0	10	/HPF	3-5	N
					Week 4	0	10	/HPF	5-10	N
					Week 8	0	10	/HPF	15-25	A
					Wk 32/Final Visit	0	10	/HPF	10-15	A
					Unscheduled	0	10	/HPF	1-3	N
						0	10	/HPF	0-1	N
	Dunner	211109	RBX	43/Male	Screen	0	5	/HPF	NONE SEEN	N
					Week 4	0	5	/HPF	0-1	N
					Week 8	0	5	/HPF	15-25	A
					Wk 32/Final Visit	0	5	/HPF	0-1	N
	Fava	51141	RBX	30/Female	Screen	0	10	/HPF	NONE SEEN	N
					Week 4	0	10	/HPF	15-25	A
					Week 8	0	10	/HPF	15-25	A
	Liebowitz	91005	RBX	54/Female	Screen	0	10	/HPF	3-5	N
					Week 8	0	10	/HPF	INNUMERABLE	A
		91035	RBX	62/Female	Screen	0	10	/HPF	0-1	N

Table LAB16

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Urinalysis Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range High	Unit	Assay-Value	Assay Flag
WBC/HPF	Liebowitz	91035	RBX	62/Female	Week 4	0	10	/HPF	1-3	N
					Week 8	0	10	/HPF	10-15	A
	Lydiard	221130	RBX	51/Female	Screen	0	10	/HPF	1-3	N
					Week 4	0	10	/HPF	10-15	A
					Unscheduled	0	10	/HPF	1-3	N
	Nelson	141041	RBX	55/Female	Screen	0	10	/HPF	1-3	N
					Week 4	0	10	/HPF	10-15	A
					Week 8	0	10	/HPF	0-1	N
	Prover	261023	RBX	33/Female	Screen	0	10	/HPF	0-1	N
					Week 4	0	10	/HPF	10-15	A
					Week 8	0	10	/HPF	NONE SEEN	N
	Rapaport	151038	Placebo	52/Male	Screen	0	5	/HPF	10-15	A
					Week 4	0	5	/HPF	1-3	N
					Week 8	0	5	/HPF	1-3	N
					Wk 32/Final Visit	0	5	/HPF	5-10	A
					Unscheduled	0	5	/HPF	3-5	N
	Thase	181135	RBX	31/Female	Screen	0	10	/HPF	3-5	N
					Week 4	0	10	/HPF	10-15	A
					Week 8	0	10	/HPF	10-15	A

Table LAB17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Drug Screen Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range Hi	Assay Value	Assay-Flag
Amphetaimes	Liebowitz	91097	RBX	38/Female	Screen	NEGATIVE	NEGATIVE	POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE	NEGATIVE	N
Barbiturates	DuBoff	311115	Placebo	30/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE	NEGATIVE	N
Benzodiazepines	Croft	231002	RBX	40/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Unscheduled	NEGATIVE	NEGATIVE	POSITIVE	A
	DuBoff	311017	RBX	54/Male	Screen	NEGATIVE	NEGATIVE	POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE	NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE	NEGATIVE	N
					Unscheduled	NEGATIVE	NEGATIVE	POSITIVE	A
								NEGATIVE	N
								POSITIVE	A
	Fava	51114	RBX	54/Female	Screen	NEGATIVE	NEGATIVE	POSITIVE	A
					Unscheduled	NEGATIVE	NEGATIVE	POSITIVE	A
	Helfing	81052	RBX	39/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
	Hoopes	271045	RBX	18/Male	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A

Table LAB17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Drug Screen Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range Hi	Assay Value	Assay-Flag
Benzodiazepines	Lydiard	221033	RBX	44/Male	Screen	NEGATIVE	NEGATIVE	POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE	NEGATIVE	N
					Unscheduled	NEGATIVE	NEGATIVE	POSITIVE	A
								NEGATIVE	N
								POSITIVE	A
	Munjack	131012	Placebo	42/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
					Wk 32/Final Visit	NEGATIVE	NEGATIVE	NEGATIVE	N
	Smith	281101	RBX	40/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
	Walsh	171027	RBX	52/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
Cocaine Metabolites	Smith	281101	RBX	40/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
Marijuana Metabolites	Liebowitz	91006	RBX	44/Female	Screen	NEGATIVE	NEGATIVE	POSITIVE	A
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
Opiates	Clayton	31111	RBX	37/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
	Croft	231002	RBX	40/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N

Table LAB17

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Post Baseline Drug Screen Values Exceeding Normal Ranges
All Enrolled Patients

Date Produced: January 15, 2001

Assay	Inv.	Patient	Trtmnt in Blinded Phase	Age/Sex	Visit	Normal Range Low	Normal Range Hi	Assay Value	Assay-Flag
Opiates	Croft	231002	RBX	40/Female	Unscheduled	NEGATIVE	NEGATIVE	POSITIVE	A
	Helfing	81004	Placebo	43/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	NEGATIVE	N
					Wk 32/Final Visit	NEGATIVE	NEGATIVE	POSITIVE	A
	Liebowitz	91006	RBX	44/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A
Proproxyphene	Smith	281107	RBX	61/Female	Screen	NEGATIVE	NEGATIVE	NEGATIVE	N
					Week 8	NEGATIVE	NEGATIVE	POSITIVE	A

Table ECG1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Screen	Week 4	Week 8/ Final
PR interval (msec)	Mean	154.3	151.4	150.0
	SD	21.3	19.5	18.7
	n	128	105	111
	Min	109	104	113
	Max	219	221	219
RR interval (msec)	Mean	925.7	742.6	741.4
	SD	143.5	114.0	97.9
	n	128	105	111
	Min	652	545	498
	Max	1301	1514	961
QRS interval	Mean	86.7	86.0	85.7

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Screen	Week 4	Week 8/ Final
QRS interval	SD	10.8	11.0	11.1
	n	128	105	111
	Min	69	63	67
	Max	162	161	170
QT interval (msec)	Mean	383.9	354.3	355.5
	SD	27.0	22.2	24.0
	n	128	105	111
	Min	298	293	296
	Max	448	412	441
QTc interval (msec) Bazett correction	Mean	401.1	413.0	414.3
	SD	22.5	19.3	19.5

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Screen	Week 4	Week 8/ Final
QTc interval (msec) Bazett correction	n	128	105	111
	Min	341	340	360
	Max	458	455	466
QTc interval (msec) Fredericia correction	Mean	395.0	392.2	393.4
	SD	19.6	16.6	17.9
	n	128	105	111
	Min	338	338	357
	Max	448	433	457
Heart rate (bpm)	Mean	66.4	82.4	82.4
	SD	10.2	10.4	10.9
	n	128	105	111

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG1

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Visit, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Screen	Week 4	Week 8/ Final
Heart rate (bpm)	Min	46	41	63
	Max	92	110	120

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 4	Week 8/ Final
PR interval (msec)	Baseline mean	155.7	155.0
	Mean Change	-4.3	-5.0
	SD of Change	15.9	16.1
	n	105	111
	Min	-43	-48
	Max	39	64
	P-value	0.0062	0.0014
RR interval (msec)	Baseline mean	927.8	923.3
	Mean Change	-185.1	-181.8
	SD of Change	146.4	130.9
	n	105	111

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 4	Week 8/ Final
RR interval (msec)	Min	-574	-562
	Max	213	162
	P-value	0.0000	0.0000
QRS interval	Baseline mean	86.9	86.8
	Mean Change	-0.9	-1.1
	SD of Change	7.2	7.2
	n	105	111
	Min	-25	-25
	Max	20	13
	P-value	0.1972	0.1125
QT interval (msec)	Baseline mean	383.4	383.9

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 4	Week 8/ Final
QT interval (msec)	Mean Change	-29.0	-28.4
	SD of Change	23.5	25.0
	n	105	111
	Min	-100	-95
	Max	45	37
	P-value	0.0000	0.0000
QTc interval (msec) Bazett correction	Baseline mean	400.3	401.5
	Mean Change	12.7	12.8
	SD of Change	20.9	22.2
	n	105	111
	Min	-43	-27

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 4	Week 8/ Final
QTc interval (msec) Bazett correction	Max	62	71
	P-value	0.0000	0.0000
QTc interval (msec) Fredericia correction	Baseline mean	394.3	395.3
	Mean Change	-2.1	-1.8
	SD of Change	16.4	19.0
	n	105	111
	Min	-45	-37
	Max	55	49
	P-value	0.2021	0.3121
Heart rate (bpm)	Baseline mean	66.5	66.5
	Mean Change	16.0	15.9

(CONTINUED)

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG - Summary Statistics of Change from Baseline, Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 4	Week 8/ Final
Heart rate (bpm)	SD of Change	11.3	10.6
	n	105	111
	Min	-8	-17
	Max	45	44
	P-value	0.0000	0.0000

Note: All comments on the results are based on cardiologist's interpretation.

Table ECG3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG Result: Normal/Abnormal Frequencies from Screen to Week 8/Final Visit - Open Phase
All Enrolled Patients

Date Produced: January 15, 2001

Screen	Week 8/Final Visit	n	%
Normal	Normal	98	99.0
	Abnormal	1	1.0
	Total Reported	99	100.0
	Not Reported	17	
Abnormal	Normal	3	25.0
	Abnormal	9	75.0
	Total Reported	12	100.0

Note: Normal/abnormal is based on cardiologist's interpretation.

Table ECG4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Treatment Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
PR interval (msec)	Mean	153.3	150.6	154.3	151.8
	SD	16.2	15.2	16.9	18.0
	n	24	22	21	22
	Min	123	124	123	119
	Max	195	188	180	195
RR interval (msec)	Mean	741.9	720.2	748.6	843.8
	SD	103.4	70.6	105.3	112.3
	n	24	22	21	22
	Min	572	623	559	627
	Max	956	860	915	1031
QRS interval	Mean	91.4	84.0	91.7	84.9

(CONTINUED)

Table ECG4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Treatment Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
QRS interval	SD	19.3	5.0	19.9	7.3
	n	24	22	21	22
	Min	75	71	73	76
	Max	170	98	166	110
QT interval (msec)	Mean	352.2	349.7	353.0	373.3
	SD	24.3	20.5	25.3	26.0
	n	24	22	21	22
	Min	302	314	307	322
	Max	410	382	401	416
QTc interval (msec) Bazett correction	Mean	410.4	412.8	409.8	407.6
	SD	20.9	15.9	21.0	19.1

(CONTINUED)

Table ECG4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Treatment Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
QTc interval (msec) Bazett correction	n	24	22	21	22
	Min	360	381	378	381
	Max	456	446	449	450
QTc interval (msec) Fredericia correction	Mean	389.8	390.4	389.7	395.5
	SD	18.6	15.6	18.5	17.8
	n	24	22	21	22
	Min	357	357	366	365
	Max	423	416	429	437
Heart rate (bpm)	Mean	82.4	84.0	81.9	72.4
	SD	11.0	8.0	12.1	10.5
	n	24	22	21	22

(CONTINUED)

Table ECG4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics by Treatment Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 8		Week 32/Final Visit	
		RBX	Placebo	RBX	Placebo
Heart rate (bpm)	Min	63	70	66	58
	Max	105	96	107	96

Table ECG5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics of Change from End of Week 8 to Final Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 32/Final Visit	
		RBX	Placebo
PR interval (msec)	Mean baseline	151.1	150.6
	Mean change	3.1	1.2
	SD of change	12.2	15.2
	n	21	22
	Min change	-32	-25
	Max change	23	29
	P-value	0.2513	0.7189
RR interval (msec)	Mean baseline	746.5	720.2
	Mean change	2.1	123.5
	SD of change	66.6	100.5
	n	21	22

(CONTINUED)

Note: Baseline for this analysis is end of week 8.

Table ECG5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics of Change from End of Week 8 to Final Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 32/Final Visit	
		RBX	Placebo
RR interval (msec)	Min change	-159	-51
	Max change	117	287
	P-value	0.8869	0.0000
QRS interval	Mean baseline	91.8	84.0
	Mean change	-0.0	0.9
	SD of change	6.3	8.0
	n	21	22
	Min change	-13	-7
	Max change	9	28
	P-value	0.9727	0.6004

(CONTINUED)

Note: Baseline for this analysis is end of week 8.

Table ECG5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics of Change from End of Week 8 to Final Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 32/Final Visit	
		RBX	Placebo
QT interval (msec)	Mean baseline	352.8	349.7
	Mean change	0.3	23.6
	SD of change	26.2	18.0
	n	21	22
	Min change	-55	-20
	Max change	41	60
	P-value	0.9607	0.0000
QTc interval (msec) Bazett correction	Mean baseline	409.6	412.8
	Mean change	0.1	-5.2
	SD of change	25.0	24.1
	n	21	22

(CONTINUED)

Note: Baseline for this analysis is end of week 8.

Table ECG5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics of Change from End of Week 8 to Final Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 32/Final Visit	
		RBX	Placebo
QTc interval (msec) Bazett correction	Min change	-43	-38
	Max change	48	69
	P-value	0.9794	0.3201
QTc interval (msec) Fredericia correction	Mean baseline	389.5	390.4
	Mean change	0.2	5.1
	SD of change	24.5	18.5
	n	21	22
	Min change	-47	-31
	Max change	43	59
	P-value	0.9650	0.2097

(CONTINUED)

Note: Baseline for this analysis is end of week 8.

Table ECG5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG: Summary Statistics of Change from End of Week 8 to Final Visit, Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Variable		Week 32/Final Visit	
		RBX	Placebo
Heart rate (bpm)	Mean baseline	81.7	84.0
	Mean change	0.2	-11.6
	SD of change	6.7	9.5
	n	21	22
	Min change	-12	-30
	Max change	13	7
	P-value	0.8983	0.0000

Note: Baseline for this analysis is end of week 8.

Table ECG6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

ECG Result: Normal/Abnormal Frequencies from week 8 to Week 32/Final Visit - Blinded Phase
All Enrolled Patients

Date Produced: January 15, 2001

Week 8	Week 32/Final Visit	RBX (N=24)		Placebo (N=22)	
		n	%	n	%
Normal	Normal	17	100.0	21	100.0
	Total Reported	17	100.0	21	100.0
	Not Reported	2			
Abnormal	Abnormal	4	100.0	1	100.0
	Total Reported	4	100.0	1	100.0
	Not Reported	1			

Note: Normal/abnormal is based on cardiologist's interpretation.

Table ECG7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Abnormal ECG ResultS
All Enrolled Patients

Date Produced: January 15, 2001

Trtmnt in Blinded Phase	Inv. Name	Patient Number	Age/ Sex	Visit	Normal/ Abnormal	ECG Change	Clinical Relevance	Heart Rate	PR Int. Mean	RR Int. Mean	QRS Int. Mean	QT Int. Mean	QTc Int. Bazett	QTc Int. Frid.	Rhythm (expanded)	Arrhy-thmia	Conduction	ADP Myocardial Infarction
RBX	Amsterdam	11065	59/M	SCREEN	NORMAL	NA	NA	51	177	1177	100	422	389	400	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 4	ABNORMAL	DETERIORATED	CLINICALLY IRRELEVANT	75	172	809	95	366	407	393	NORMAL SINUS RHYTHM		IRBBB	ABSENT
																	LPH	ABSENT
		11133	41/M	SCREEN	ABNORMAL	NA	CLINICALLY RELEVANT	86	159	702	83	318	380	358	NORMAL SINUS RHYTHM		NORMAL	INFERIOR (2), 3, F
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY RELEVANT	96	161	625	83	321	407	376	NORMAL SINUS RHYTHM		NORMAL	INFERIOR (2), 3, F
				WEEK 8	ABNORMAL	DETERIORATED	CLINICALLY RELEVANT	120	159	498	83	296	420	373	SINUS TACHYCARDIA		NORMAL	INFERIOR (2), 3, F
	Croft	231079	65/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	46	179	1301	92	415	364	380	SINUS BRADYCARDIA		LAH	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	41	174	1514	94	412	340	362	SINUS BRADYCARDIA	VPC	LAH	ABSENT
				WEEK 8	ABNORMAL	IMPROVED	CLINICALLY IRRELEVANT	71	153	876	92	392	424	413	NORMAL SINUS RHYTHM		LAH	ABSENT
		231119	56/F	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	62	170	978	83	371	375	374	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	86	175	697	80	316	378	356	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	63	174	956	76	352	360	357	NORMAL SINUS RHYTHM		LAH	ABSENT
				WK 32/FINAL	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	76	180	797	77	340	381	367	NORMAL SINUS RHYTHM		LAH	ABSENT
	Delgado	41094	64/F	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	58	163	1025	116	421	416	417	NORMAL SINUS RHYTHM		RBBB	ABSENT

Note: All comments on the results are based on cardiologists's interpretation.

Table ECG7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Abnormal ECG ResultS
All Enrolled Patients

Date Produced: January 15, 2001

Trtmnt in Blinded Phase	Inv. Name	Patient Number	Age/ Sex	Visit	Normal/ Abnormal	ECG Change	Clinical Relevance	Heart Rate	PR Int. Mean	RR Int. Mean	QRS Int. Mean	QT Int. Mean	QTc Int. Bazett	QTc Int. Frid.	Rhythm (expanded)	Arrhy-thmia	Conduction	ADP Myocardial Infarction
RBX	Delgado	41094	64/F	WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	65	176	924	125	394	410	404	NORMAL SINUS RHYTHM		RBBB	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	65	158	932	117	410	424	419	NORMAL SINUS RHYTHM		RBBB	ABSENT
				WK 32/FINAL	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	69	159	872	119	398	427	417	NORMAL SINUS RHYTHM		RBBB	ABSENT
	DuBoff	311017	54/M	SCREEN	NORMAL	NA	NA	61	151	987	80	390	393	392	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 4	ABNORMAL	DETERIORATED	CLINICALLY IRRELEVANT	90	142	670	82	338	413	387	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 8	NORMAL	NO CHANGE	NA	84	136	718	75	336	396	375	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WK 32/FINAL	NORMAL	NO CHANGE	NA	82	133	733	79	332	388	369	NORMAL SINUS RHYTHM		NORMAL	ABSENT
	Ferguson	241031	61/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	70	155	870	99	427	458	447	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 8	ABNORMAL	DETERIORATED	CLINICALLY IRRELEVANT	84	219	718	107	375	443	419	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
	Liebowitz	91035	62/F	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	86	148	699	81	335	400	377	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	95	137	633	82	330	415	385	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	94	139	639	84	342	428	397	NORMAL SINUS RHYTHM		LAH	ABSENT

Note: All comments on the results are based on cardiologists's interpretation.

Table ECG7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Abnormal ECG ResultS
All Enrolled Patients

Date Produced: January 15, 2001

Trtmnt in Blinded Phase	Inv. Name	Patient Number	Age/ Sex	Visit	Normal/ Abnormal	ECG Change	Clinical Relevance	Heart Rate	PR Int. Mean	RR Int. Mean	QRS Int. Mean	QT Int. Mean	QTc Int. Bazett	QTc Int. Frid.	Rhythm (expanded)	Arrhy-thmia	Conduction	ADP Myocardial Infarction
RBX	Liebowitz	91137	40/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	54	219	1100	103	393	375	381	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	97	203	617	111	342	436	402	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				WEEK 8	NORMAL	IMPROVED	NA	69	198	873	112	370	396	387	NORMAL SINUS RHYTHM		NORMAL	ABSENT
	Londborg	101010	51/F	SCREEN	NORMAL	NA	NA	66	171	908	95	427	448	441	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				UNSCHEDULED	NORMAL	NO CHANGE	NA	71	161	852	92	401	435	423	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 4	NORMAL	NO CHANGE	NA	81	169	742	92	392	455	433	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 8	ABNORMAL	DETERIORATED	CLINICALLY IRRELEVANT	80	180	749	90	391	452	431	NORMAL SINUS RHYTHM		NORMAL	ABSENT
	McGrath	111171	50/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	72	202	830	82	351	386	374	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				UNSCHEDULED	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	72	217	837	82	366	400	388	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	83	221	725	79	328	385	365	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				WEEK 8	NORMAL	IMPROVED	NA	84	200	716	82	331	392	370	NORMAL SINUS RHYTHM		NORMAL	ABSENT

Note: All comments on the results are based on cardiologists's interpretation.

Table ECG7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Abnormal ECG ResultS
All Enrolled Patients

Date Produced: January 15, 2001

Trtmnt in Blinded Phase	Inv. Name	Patient Number	Age/ Sex	Visit	Normal/ Abnormal	ECG Change	Clinical Relevance	Heart Rate	PR Int. Mean	RR Int. Mean	QRS Int. Mean	QT Int. Mean	QTc Int. Bazett	QTc Int. Frid.	Rhythm (expanded)	Arrhy-thmia	Conduction	ADP Myocardial Infarction
RBX	Oldroyd	321087	55/M	SCREEN	ABNORMAL	NA	CLINICALLY RELEVANT	50	169	1197	162	440	402	414	NORMAL SINUS RHYTHM		LAH	ABSENT
																	RBBB	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY RELEVANT	74	178	810	161	385	428	413	NORMAL SINUS RHYTHM		LAH	ABSENT
																	RBBB	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY RELEVANT	82	159	730	170	367	430	408	NORMAL SINUS RHYTHM		LAH	ABSENT
																	RBBB	ABSENT
				WK 32/FINAL	ABNORMAL	NO CHANGE	CLINICALLY RELEVANT	75	170	799	166	398	445	429	NORMAL SINUS RHYTHM		LAH	ABSENT
																	RBBB	ABSENT
	Trivedi	191014	47/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	65	210	922	110	361	376	370	NORMAL SINUS RHYTHM		FIRST DEGREE BLOCK	ABSENT
				WEEK 4	NORMAL	IMPROVED	NA	88	197	684	92	331	401	376	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 8	NORMAL	NO CHANGE	NA	91	195	655	92	336	415	386	NORMAL SINUS RHYTHM		NORMAL	ABSENT
	Zajecka	201067	31/M	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	55	172	1094	82	366	350	356	NORMAL SINUS RHYTHM		IRBBB	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	68	139	881	92	361	384	377	NORMAL SINUS RHYTHM		IRBBB	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	75	143	799	92	376	421	405	NORMAL SINUS RHYTHM		IRBBB	ABSENT
				WK 32/FINAL	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	70	158	862	83	350	378	368	NORMAL SINUS RHYTHM		IRBBB	ABSENT

Note: All comments on the results are based on cardiologists's interpretation.

Table ECG7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Listing of Patients with Abnormal ECG ResultS
All Enrolled Patients

Date Produced: January 15, 2001

Trtmnt in Blinded Phase	Inv. Name	Patient Number	Age/ Sex	Visit	Normal/ Abnormal	ECG Change	Clinical Relevance	Heart Rate	PR Int. Mean	RR Int. Mean	QRS Int. Mean	QT Int. Mean	QTc Int. Bazett	QTc Int. Frid.	Rhythm (expanded)	Arrhy-thmia	Conduction	ADP Myocardial Infarction
Placebo	Helfing	81003	65/F	SCREEN	ABNORMAL	NA	CLINICALLY IRRELEVANT	67	141	899	94	376	396	390	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 4	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	84	162	719	87	332	392	371	NORMAL SINUS RHYTHM		LAH	ABSENT
				WEEK 8	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	93	149	646	82	342	426	396	NORMAL SINUS RHYTHM		LAH	ABSENT
				WK 32/FINAL	ABNORMAL	NO CHANGE	CLINICALLY IRRELEVANT	87	155	688	82	322	388	365	NORMAL SINUS RHYTHM		LAH	ABSENT
	Rapaport	151096	60/M	SCREEN	NORMAL	NA	NA	57	155	1055	104	400	389	393	NORMAL SINUS RHYTHM		NORMAL	ABSENT
				WEEK 4	ABNORMAL	DETERIORATED	CLINICALLY IRRELEVANT	81	133	738	83	341	397	377	ECTOPIC ATRIAL RHYTHM		NORMAL	ABSENT
				WEEK 8	NORMAL	NO CHANGE	NA	80	151	746	98	355	412	392	NORMAL SINUS RHYTHM	APC	NORMAL	ABSENT
				WK 32/FINAL	NORMAL	NO CHANGE	NA	65	147	925	92	367	381	376	NORMAL SINUS RHYTHM		NORMAL	ABSENT

Note: All comments on the results are based on cardiologists's interpretation.

Table ECG8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on ECG Results (Clinical Evaluation) at Screen - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	ECG Results (Normal/ Abnormal)	Comment
Amsterdam	11065	Abnormal	NCS
	11133	Abnormal	NCS PER PI
Croft	231079	Abnormal	NOT CLINICALLY SIGNIFICANT
Delgado	41094	Abnormal	RBBB - FOUND TO BE NCS PER PREMIER
Ferguson	241031	Abnormal	NOT CLINICALLY SIGNIFICANT
Helfing	81003	Abnormal	POSSIBLE LEFT ATRIAL ENLARGEMENT, NCS PER PI OK FOR STUDY PER PI
Liebowitz	91035	Abnormal	NOT CLINICALLY SIGNIFICANT
	91137	Abnormal	PT'S ECG HAS ABNORMAL FINDINGS APPROVED BY PNU TO ENTER STUDY
McGrath	111171	Abnormal	ABNORMAL EKG - NOT CLINICALLY SIGNIFICANT
Moreines	121007	Abnormal	BORDERLINE ABNORMAL-HISTORY OF MITRAL VALVE PROLAPSE
Nelson	141041	Abnormal	NOT CLINICALLY SIGNIFICANT
Oldroyd	321055	Abnormal	SINUS BRADYCARDIA-NAS
	321087	Abnormal	NCS:RIGHT BUNDLE BRANCH BLOCK; NCS LEFT ATRIA FASCICULAR BLOCK; BRADYCARDIA

Table ECG8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on ECG Results (Clinical Evaluation) at Screen - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	ECG Results (Normal/ Abnormal)	Comment
Trivedi	191013	Abnormal	NOT CLINICALLY SIGNIFICANT PER DR MYER, NORMAL PER PREMIER
Zajecka	201067	Abnormal	NOT CLINICALLY SIGNIFICANT

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Amsterdam	11065	SCID NOT DONE PRIOR TO PROZAC, PER SPONSOR DIRECTIVE DONE RETROSPECTIVELY
	11066	2B. SCID NOT DONE PRIOR TO PROZAC TREATMENT. PER SPONSOR APPROVAL, THE SCID WAS DONE RETROSPECTIVELY
	11133	SCID NOT DONE PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL, SCID WAS DONE RETROSPECTIVELY
	11134	SCID NOT ADMINISTERED WHEN PATIENT ON PROZAC TREATMENT, PER SPONSOR APPROVAL SCID ADMINISTERED RETROSPECTIVELY.
	11159	2B. SCID NOT DONE PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL, THE SCID WAS DONE RETROSPECTIVELY
	11160	PAST MDD EPISODE NOT DONE PRIOR TO PROZAC RX, PER SPONSOR'S DIRECTIVE BUT WAS DONE RETROSPECTIVELY
	11167	2B. SCID NOT DONE PRIOR TO PROZAC, PER SPONSOR, SCID DONE RETROSPECTIVELY
Clayton	31019	RE: 2A, SCID WAS DONE RETROSPECTIVELY.
	31020	RE: 2A, SCID WAS DONE RETROSPECTIVELY
	31047	RE: 2A-SCID WAS DONE RETROSPECTIVELY
	31048	RE: 2A, SCID WAS DONE RETROSPECTIVELY
	31111	RE:2A-SCID WAS DONE RETROSPECTIVELY
	31112	RE: 2A - SCID WAS DONE RETROSPECTIVELY

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Croft	231001	INCLUSION ITEM 2B-PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO TIME PERIOD PRIOR TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSES OF MAJOR DEPRESSIVE DISORDER PRESENT
	231002	INCLUSION ITEM 2B-PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO TIME PERIOD PRIOR TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER PRESENT
	231079	INCLUSION ITEM 2B - PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO TIME PERIOD PRIOR TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER PRESE
	231080	INCLUSION ITEM 2B-PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO PERIOD TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER PRESENT PRIOR TO S
	231119	INCLUSION ITEM 2B-PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO TIME PERIOD PRIOR TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER PRESENT
	231120	INCLUSION ITEM 2B-PAST MAJOR DEPRESSIVE EPISODE MODULE OF SCID COMPLETED REFERRING TO TIME PERIOD PRIOR TO START OF FLUOXETINE TO RETROSPECTIVELY CONFIRM DIAGNOSIS OF MAJOR DEPRESSIVE DISORDER PRESENT
Delgado	41070	DOCUMENTION OF SCID PRIOR TO FLUOXETINE TX. NOT AVAILABLE. PAST MDD EPISODE OF SCID ADMINISTERED DURING SCREENING PERIOD OF THIS STUDY WITH PERMISSION FROM SPONSER.
DuBoff	311017	SCID WAS COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL
	311018	2B SCID COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL
	311115	2B SCID COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
DuBoff	311116	2B SCID COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL
Dunner	211039	FULL SCID NOT DONE PRIOR TO PROZAC TREATMENT. PER SPONSOR, THE PAST MDE MODULE DONE TO DETERMINE MDD DIAGNOSIS PRIOR TO PROZAC TREATMENT. (INCLUSION CRITERIA 2B) LATE ENTRY
	211109	FULL SCID NOT DONE PRIOR TO PROZAC TREATMENT, PER SPONSOR THE PAST MDE MODULE DONE TO DETERMINE MDD DIAGNOSIS PRIOR TO PROZAC TREATMENT. INCLUSION CRITERIA #2B
	211145	FULL SCID NOT DONE PRIOR TO PROZAC TREATMENT-PER SPONSOR THE PAST MDE MODULE DONE TO DETERMINE MDD DIAGNOSIS PRIOR TO PROZAC TREATMENT. INCLUSION CRITERIA #2B.
	211146	FULL SCID NOT DONE PRIOR TO PROZAC TREATMENT. PER SPONSOR, THE PAST MDE MODULE DONE TO DETERMINE MDD DIAGNOSIS PRIOR TO PROZAC TREATMENT. INCLUSION CRITERIA #2B
	211147	FULL SCID NOT DONE PRIOR TO PROZAC TREATMENT-PER SPONSOR THE PAST MDE MODULE DONE TO DETERMINE MDD DIAGNOSIS PRIOR TO PROZAC TREATMENT. INCLUSION CRITERIA #2B.
Fava	51113	PATIENT HAS BEEN TAKING PRESCRIBED TYLENOL III, WHICH EXPLAINS THE POSITIVE OPIATE LEVEL FOUND IN HER BLOOD SCREEN. MDD MODULE FOR POST EPISODES COMPLETED RETROSPECTIVELY
	51114	SCID NOT DONE PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL SCID, ADMINISTERED RETROSPECTIVELY (MDD PAST EPISODE).
	51142	PAST MDD MODULE ADMINISTERED RETROSPECTIVELY TO FLUOXETINE TREATMENT.
Ferguson	241031	SCID WAS COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Ferguson	241032	SCID WAS COMPLETED RETRASPECTIVELY PER SPONSOR APPROVAL
	241073	SCID WAS COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL,DONE AT THE WK 8/EARLY TERMINATION VISIT
	241074	SCID WAS COMPLETE PETROSPECTIVELY PER SPONSOR APPROVAL, COMPLETED AT WEEK 5
Gilmer	61082	REGARDING ENTRY 2B, PAST MDD MODULE COMPLETED. RETROSPECTIVE TO PROZAC USAGE PER SPONSOR'S REQUEST
Halbreich	71077	13- ECG REPEATED ON 11/3/99 SENT TO PREMIER THAT DATE-RESULTS NORMAL
Helfing	81052	+ OPIATES AT SCREEN-PT STATED SHE TOOK VICODIN X3 FOR LOW BACK PAIN. WILL CALL SPONSOR FOR APPROVAL. LATE ENTRY 11/5/99: SPONSOR ALLOWED PT INTO STUDY LATE ENTRY Q.2B-PT DON'T HAVE A COMPLETE SCID DON
	81075	LATE ENTRY FOR 2B: THE PT DID NOT HAVE A COMPLETE SCID DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR THE PAST MDE MODULE OF THE SCID WAS COMPLETED TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREA
	81076	LATE ENTRY FOR QUESTION 2B: THE PATIENT DID NOT HAVE A COMPLETE SCID DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR THE PAST MDE MODULE OF THE SCID WAS DONE TO CONFIRM PRESENCE OF MDD PRIOR TO PROZAC
	81103	PT DID NOT HAVE COMPLETE SCID DONE PRIOR TO FLUOXETINE TREATMENT. PER SPONSOR, THE PAST MDE MODULE WAS DONE TO CONFIRM THAT MDD WAS PRESENT PRIOR TO FLUOXETINE TREATMENT
Hoopes	271021	RE:QUESTION 2B, CURRENT EPISODE OF DEPRESSION IS THE SAME EPISODE AS WHEN PROZAC WAS FIRST PRESCRIBED. SCID WAS DONE RETROSPECTIVELY FOR WHEN PT. FIRST DIAGNOSED.

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Hoopes	271022	LATE ENTRY-A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR A PAST MDE MODULE OF THE SCID HAS BEEN DONE TO VERIFY A DIAGNOSIS OF MDD PRIOR TO PROZAC TREATMENT.
	271045	LATE ENTRY-A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT-PER THE SPONSOR A PAST MDE MODULE OF THE SCID HAS BEEN DONE TO VERIFY A DIAGNOSIS OF MDD PRIOR TO PROZAC TREATMENT.
Liebowitz	91035	RE: 2B PAST MDD MODULE COMPLETED AT SUBSEQUENT VISIT DONE ON 12-10-99 BY MRL - AFTER SCREENING PERIOD. PAST PATIENT'S PARTICIPATION IN STUDY PATIENT COMPLETED STUDY PRIOR TO PAST MDD MODULE BEING COM
	91036	(2B) PAST MDD MODULE NOT COMPLETED FOR THIS PATIENT IN ERROR. PATIENT ENTERED STUDY; MD WAS GOING TO COMPLETE PAST MDD. MODULE AT A SUBSEQUENT VISIT BUT PATIENT NEVER RETURNED TO CLINIC.
	91097	PAST MDD MODULE OF SCID DONE RETROSPECTIVE TO PROZAC TX-PER SPONSOR DIRECTIVE. MODULE E & F SCID AFTER PT. ENTERED STUDY
	91137	PAST MDD MODULE WAS COMPLETE RETROSPECTIVE TO PROZAC TREATMENTAS PER SPONSOR'S DIRECTIVE.MODULES E & F NOT COMPLETED AT SCREEN VISIT,WILL BE COMPLETED AT SUBSEQUENT VISIT. PATIENTS ECG HAS ABNORMAL FI
	91138	SCID COMPLETED RETROSPECTIVE TO PROZAC USE, AS PER SPONSOR'S DIRECTIVE.
Londborg	101044	LATE ENTRY: A COMPLETE SCID WAS NOT DONE PRIOR TO FLUOXETINE TX. THE CURRENT COMPLETE SCID DONE TO CONFIRM THIS PRESENT EPISODE ALSO REFLECTS THAT THE SYMPTOMOLOGY OF MDD WAS PRESENT PRIOR TO FLUOXET
Lydiard	221033	SCID COMPLETED DAY OF SCREEN VISIT 1999-11-18 TO CONFIRM MAJOR DEPRESSION DIAGNOSIS
	221034	THE SCID WAS PERFORMED AT THE SCREEN VISIT TO VERIFY MDD DIAGNOSIS.

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Lydiard	221129	SCID COMPLETED DAY OF SCREEN VISIT 2000-02-15 TO CONFIRM MAJOR DEPRESSION DIAGNOSIS
	221130	THE SCID WAS PERFORMED AT THE SCREEN VISIT ON 03-06-00.
McGrath	111057	PATIENT'S URINE TOXICOLOGY POSITIVE FOR OPIATES.SPOKE WITH SPONSOR WHO ADVISED REPEAT OF URINE.URINE NEGATIVE 11/2/99. PAST MDD WAS OMITTED FROM SCID
Moreines	121007	SCID DONE RETROSPECTIVELY AS PER SPONSOR DIRECTION
Munjack	131011	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL
	131012	SCID DONE RETROSPECTIVELY PER SPONOR'S APPROVAL
	131071	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL.
	131072	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL.
	131125	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL
	131126	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL.
	131143	SCID DONE RETROSPECTIVELY PER SPONSOR'S APPROVAL
	131144	SCID USED RETROSPECTIVELY PER SPONSOR'S APPROVAL
Oldroyd	321055	RE SCID WAS COMPLETED RETROSPECTIVELY PER SPONOR APPROVAL

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Oldroyd	321087	SCID WAS COMPLETED RETROSPECTIVELY PER SPONSOR APPROVAL. HISTORY OF GLAUCOMA IS STABLE AND PATIENT IS FOLLOWED BY THE OPTHALMOLOGIST. SPONSORS WAS INFORMED OF PATIENT'S MEDICAL CONDITION.
Rapaport	151037	2B:"PAST MAJOR DEPRESSIVE EPISODE COMPLETELY PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL"
	151038	2B: PAST MAJOR DEPRESSIVE EPISODE COMPLETED PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL
	151085	2B: PAST MAJOR DEPRESSIVE EPISODE OF SCID COMPLETED PRIOR TO PROZAC TREATMENT. RETROSPECTIVELY, PER SPONSOR APPROVAL
	151086	2B: PAST MAJOR DEPRESSIVE EPISODE COMPLETED PRIOR TO PROZAC TREATMENT. PER SPONSOR APPROVAL
	151095	2B: PAST MAJOR DEPRESSIVE DISORDER IN SCID COMPLETED PRIOR TO PROZAC TREATMENT, RETROSPECTIVELY, PER SPONSOR APPROVAL
	151096	2B: PAST MAJOR DEPRESSIVE EPISODE OF SCID COMPLETED PRIOR TO PROZAC TREATMENT RETROSPECTIVELY, PER SPONSOR APPROVAL
	151099	2B: PAST MDD OF SCID COMPLETED PRIOR TO PROZAC TREATMENT, RETROSPECTIVELY PER SPONSOR APPROVAL.
	151100	2B: PAST MAJOR DEPRESSIVE EPISODE OF SCID COMPLETED, RETROSPECTIVELY, PRIOR TO PROZAC TREATMENT,PER SPONSOR APPROVAL.
	151117	2B: PAST MAJOR DEPRESSIVE EPISODE OF SCID COMPLETED PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL.
	151118	2B:PAST MDD EPISODE COMPLETED PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL.
	151153	2B:PAST MDD EPISODE COMPLETED PRIOR TO PROZAC TREATMENT, PER SPONSOR APPROVAL.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Smith	281025	DZR DIAGNOSED WITH CROHNS DISEASE IN 1991. PT HAS BEEN UNSYMPTOMATIC AND STABLE WITH THE EXCEPTION OF INFREQUENT DIARRHEA. DR SUZETTE R MACMURRAY MADE AWARE OF PT ENROLLMENT. PAST MDE OF SCID MODULE C
	281101	PAST MDE MODULE OF SCID COMPLETED IN REFERENCE TO DEPRESSION PRIOR TO PROZAC THERAPY PER SPONSOR DIRECTIVE
	281102	PAST MDE MODULE OF SCID COMPLETED IN REFERENCE TO DEPRESSION PRIOR TO PROZAC THERAPY PER SPONSOR DIRECTIVE. MODULES E AND F NOT DONE AT SCREEN VISIT. PER SPONSOR DIRECTIVE OK TO COMPLETE AT LATER DATE
	281107	PAST MDE MODULE COMPLETED IN REFERENCE TO DEPRESSION PRIOR TO BEGINNING OF PROZAC THERAPY PER SPONSOR DIRECTIVE. SCID MODULE E AND F NOT COMPLETED AT SCREEN IN ERROR. SPONSOR NOTIFIED, DIRECTIVE GIVE
	281108	PAST MDE MODULE OF SCID DONE IN REFERENCE TO TREATMENT PRIOR TO USE OF PROZAC PER SPONSOR DIRECTIVE. SCID MODULES E AND F MISSED AT SCREEN VISIT PER SPONSOR DIRECTIVE MODULE COMPLETED AT LATER DATE.
Telew	171016	LATE ENTRY: REFERENCE QUESTION 2B; A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR THE PAST MDE MODULE OF THIS SCID WAS DONE TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREA
	171027	LATE ENTRY: REFERENCE QUESTION 26; A COMPLETE SKID WAS NOT DONE PRIOR TO PROZAC TREATMENT PER THE SPONSOR THE PAST MDE MODULE OF THE SKID WAS DONE TO CONFIRM THE PRESENCE OF MAJOR DEPRESSIVE DISORDER
Thase	181083	2B SCID DONE PRIOR TO PROZAC TREATMENT PER SPONSOR APPROVAL SCID WAS ADMINISTERED RETROSPECTIVELY
	181105	PT. MEETS SCID CRITERIA OF MDD PRIOR TO FLUOXETINE USE. SCID DONE RETROSPECTIVELY
	181135	SCID NOT DONE PIROR TO PROZAC TREATMENT PER SPONSOR DIRECTIVE DONE RETROSPECTEDLY.

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Thase	181136	RE:2B SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT. PER SPONSORS APPROVAL SCID DONE RETROSPECTIVELY
Trivedi	191013	PT MEETS STUDY CRITERIA & HAS SIGNED INFORNED CONSENT. SCID DOCUMENTATION OF PT'S MDD PRIOR TO STARTING PROZAC IS NOT AVAILABLE HOWEVER, PER SPONSOR'S INSTRUCTIONS, PRIOR MDD EPISODE MODULE OF THE SCI
	191014	PT MEETS ALL CRITERIA FOR ENTRY INTO STUDY. SI CONSENT SIGNED PRIOR TO ANY PROCEDURES.
Walsh	171015	LATE ENTRY: REFERENCE QUESTION 2B; A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR THE PAST MDE MODULE OF THE SCID WAS DONE TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREAT
	171028	1) LATE ENTRY: REFERENCE QUESTION 8: PT HAS HAD A TUBAL LIGATION AND A PREGNANCY TEST NA. 2)REFERENCE QUESTION 2B: A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT.PER SPONSOR THE PAST MDE MODUL
	171061	LATE ENTRY: REFERENCE 2B, A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT PER SPONSOR THE PAST MDE MODULE OF THE SCID WAS DONE TO COMFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREATMENT
	171062	LATE ENTRY: REFERENCE QUESTION 2B; A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT. PER THE SPONSOR THE PAST MDE MODULE OF THE SCID WAS DONE TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREAT
	171063	LATE ENTRY: REFERENCE QUESTION 2B; A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT PER THE SPONSOR THE PAST MDE MODULE OF THE SKID WAS DONE TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREAT
	171064	LATE ENTRY; REFERENCE QUESTION 2B; A COMPLETE SCID WAS NOT DONE PRIOR TO PROZAC TREATMENT PER THE SPONSOR THE PAST MDE MODULE OF THIS SCID WAS DONE TO CONFIRM THE PRESENCE OF MDD PRIOR TO PROZAC TREAT
Zajecka	201067	PAST MDD SCID DONE RETROSPECTIVE TO PROZAC USAGE. PER SPONSOR DIRECTIVE.

LIST2

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Eligibility Criteria - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Comment
Zajecka	201068	PT HAS ELEVATED AST & ALT-DISCUSSED WITH MEDICAL MONITOR. OK TO ENROLL PT IN STUDY AND FOLLOW LFT'S WEEKLY.IF LFT'S CONTINUE TO RISE, WILL DROP FROM STUDY. PER SPONSOR, SCID WAS DONE, PROZAC START. P
	201092	2B) PAST MDD EPISODE ON SCID DONE RETROSPECTIVELY PER SPONSOR'S DIRECTIVE. 8) PATIENT HAS HAD HYSTERECTOMY
	201123	LATE ENTRY 5/17/00 REGARDING QUESTION #8 THAT PT. HAS MENSTRUAL CYCLE BUT INFERTILE DUE TO BLOCKED FALLOPIAN TUBES; LATE ENTRY 5/17/00 REGARDING 2B: PT DID NOT HAVE COMPLETE SCID DONE PRIOR TO PROZAC

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Amsterdam	11065	CARDIOVASCULAR	HYPERCHOLESTEROLEMIA 1993
		DERMATOLOGIC	IN REMISSIN 5 YEARS MALIGNANT MELANOMA 1994
	11066	ALLERGIC	SEASONAL ALLERGIES
		CARDIOVASCULAR	HYPERTENSION NO TREATMENT
	11133	ALLERGIC	ENVIRONMENTAL
		CARDIOVASCULAR	HIGH BLOOD PRESSURE 1993
		DERMATOLOGIC	SHINGLES 1/13/00
		HEENT/MOUTH	SINUSITIS, T AND A AGE 10, REPAIR DEVIATED SEPTUM 1984
		HEMATOLOGIC	HYPERCHOLESTEROLEMIA 1993
		MUSCULOSKELETAL	DEGENERATIVE CERVICAL DISC DISEASE 1994
		VIRAL	HERPES ZOSTER
	11134	GASTROINTESTINAL	STATUS-POST COLITIS (DATE UNKNOWN), HEMORRHOIDECTOMY 1998, INTERNAL BLOODING HEMORRHOIDS
		MUSCULOSKELETAL	1963 FOOT SURGERY SECONDARY TO POLIO, 1966 ANKLE SURGERY SECONDARY TO POLIO, 1960 KNEE SURGERY SECONDARY TO POLIO

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Inv. Name	Patient Number	Body System	Description
Amsterdam	11134	POLIO MYELITIS	1952
	11159	ALLERGIC	CODEINE
		HEENT/MOUTH	HEADACHES
		MUSCULOSKELETAL	BACK AND NECK PAIN
		RENAL/URINARY TRACT	STRESS-INDUCED URINARY INCONTINENCE
		SURGICAL HISTORY	D + C 1977
	11160	HEENT/MOUTH	EXCISION OF POLYP-EAR, AGE 54
		MUSCULOSKELETAL	TRACTION FOR HERNIATED DISC
	11167	GASTROINTESTINAL	CHOLECYSTECTOMY-1988
		METABOLIC/ENDOCRINE	HYPERCHOLESTEROLEMIA S/P-1998, IDDM-1984, S/P HYPOTHYROIDISM-1987
		MUSCULOSKELETAL	LEFT KNEE LIGAMENT REPAIR-1995, TORN RT SHOULDER CUFF/S/P-1999
		REPRODUCTIVE	S/P BREAST CYST REMOVAL-1979
Barbee	21053	ALLERGIC	DARVOCET 1985, TORADOL 1996

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
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Inv. Name	Patient Number	Body System	Description
Barbee	21053	MUSCULOSKELETAL	FRACTURE LEFT 5TH DIGIT 1983, SEVERED TENDONS LEFT HAND 1985, STRESS FRACTURE LEFT TIBIA 1987, FRACTURE LEFT TIBIA 1991
		RENAL/URINARY TRACT	KIDNEY STONES 1996
Clayton	31019	GASTROINTESTINAL	ESOPHAGOGASTRODUODENOSCOPY (EGD) TO REMOVE SWALLOWED DENTIST'S DRILL BIT
		MUSCULOSKELETAL	COSTOCHONDRITIS (ONGOING)
	31020	DERMATOLOGIC	SEBACEOUS CYSTS, POSTERIOR SCALP
		GASTROINTESTINAL	HISTORY OF GASTRIC ULCERS (LAST IN 1996-97)
		HEENT/MOUTH	GLASSES FOR READING
		HEMATOLOGIC	HISTORY OF LOW WHITE BLOOD CELL COUNT POSSIBLY DUE TO PESTICIDE EXPOSURE
		MUSCULOSKELETAL	S/P TRAUMATIC INJURY LEFT HAND, 6/97
	31047	ALLERGIC	DRUG ALLERGIES: PENICILLIN, SULFA, MORPHINE
		GASTROINTESTINAL	GAS, CONSTIPATION, ABDOMINAL PAIN-IRRITABLE BOWEL SYNDROME
		GYNECOLOGICAL	ENDOMETRIOSIS 1997, HYSTERECTOMY 1997
		HEENT/MOUTH	WEARS GLASSES

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Inv. Name	Patient Number	Body System	Description
Clayton	31047	METABOLIC/ENDOCRINE	STATUS POST BILATERAL SALPINGO OOPHORECTOMY, SO LOW SEX STERIODS-8/98
		MUSCULOSKELETAL	HISTORY OF L4-L5 HERNIATED DISC
	31048	ALLERGIC	SEASONAL ALLERGIES
		DERMATOLOGIC	ACNE
		GASTROINTESTINAL	CONSTIPATION ALTERNATING WITH DIARRHEA (IRRITABLE BOWEL SYNDROME)
		HEENT/MOUTH	CORRECTIVE LENSES
		PULMONARY	HISTORY OF SEASONAL ALLERGIES WITH ASSOCIATED BRONCHOSPASM
		RENAL/URINARY TRACT	FREQUENT URINATION
	31111	CARDIOVASCULAR	HISTORY OF NORMAL CARDIAC CATH,1999
		DRUG REACTION	NARCOTICS CAUSE NAUSEA AND VOMITING
		HEENT/MOUTH	SEASONAL ALLERGIES
		RENAL/URINARY TRACT	HYSTERECTOMY, 1998.BLADDER TACKED UP,1998
	31112	DERMATOLOGIC	REMOVAL OF SEBACIOUS CYST (L) LOWER EXTREMITY

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Medical History Descriptions - Listing by Patient
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Inv. Name	Patient Number	Body System	Description
Clayton	31112	GENITAL/URINARY	STATUS POST SPONTANEOUS VAGINAL DELIVERY X2
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM, 1996
		MUSCULOSKELETAL	TORN LIGAMENTS (L) FOOT IN FALL 9/99
Croft	231001	ALLERGIC	MOLD ALLERGIES-ONGOING
		GASTROINTESTINAL	CHRONIC CONSTIPATION, REDUNDANT COLON-ONGOING
		RENAL/URINARY TRACT	CYSTOCELE-CURRENT, URINE RETENTION-ONGOING
		REPRODUCTIVE	HISTORY OF UTERINE FIBROIDS-CURRENT, RECTOCELE-ONGOING
	231002	ALLERGIC	SEASONAL ALLERGIES (CURRENT)
		GASTROINTESTINAL	GASTROESOPHOGEAL REFLUX DISEASE (CURRENT)
		HEENT/MOUTH	SINUS HEADACHES (CURRENT)
		REPRODUCTIVE	PARTIAL HYSTERECTOMY
	231079	ALLERGIC	SEASONAL ALLERGIES
		CARDIOVASCULAR	PALPATIONS HYPERTENSION - SINCE 1988 WAS ON B/P MEDS UNTIL MD TOLD HIM TO STOP HAS NOT BEEN ON MEDS FOR SEVERAL YEARS, NO MEDS PER PATIENT AND HIS MD

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Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Croft	231079	GASTROINTESTINAL	CONSTIPATION
		HEENT/MOUTH	NEARSIGHTED
		MUSCULOSKELETAL	TOES AMPUTATED ON BOTH FEET
		PULMONARY	PULMONARY FIBROSIS
	231080	ALLERGIC	SEASONAL ALLERGIES
		CARDIOVASCULAR	HISTORY OF SKIPPED BEATS (CARDIAC ARRYTHMIA) AND ABNORMAL EKG 5 YEARS AGO, HAD NORMAL STRESS TEST
		DERMATOLOGIC	LEFT LEG MALIGNANT MELANOMA, REMOVED
		GASTROINTESTINAL	SURGERY IN 1997 FOR DIVERTICULITIS WITH SECONDARY PERFORATED COLON, OCCASIONAL HEARTBURN
		HEENT/MOUTH	FARSIGHTED;CHRONIC RHINORRHEA AND NASAL CONGESTION
		HEMATOLOGIC	EPISODIC ANEMIA
		MUSCULOSKELETAL	CHRONIC LOW BACK PAIN,ONGOING OSTEOARTHRITIS
		NEUROLOGIC	SINUS HEADACHES AND MIGRAINES
		REPRODUCTIVE	BILATERAL BENIGN BREAST LUMPS,CURRENT FIBROCYSTIC BREASTS,OVARIAN CYST REMOVED 1995

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Medical History Descriptions - Listing by Patient
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Inv. Name	Patient Number	Body System	Description
Croft	231119	ALLERGIC	DEMEROL, ENVIRONMENTAL ALLERGIES
		DERMATOLOGIC	DRY SKIN-ONGOING. INCISION AND DRAINAGE OF LEFT HAND DUE TO SPIDER BITE-RESOLVED
		GASTROINTESTINAL	PILONIDAL CYST, EPISODIC CONSTIPATION
		HEENT/MOUTH	T&A, NEARSIGHTED, DEVIATED SEPTUM REPAIRED
		NEUROLOGIC	EPISODIC HEADACHES
		REPRODUCTIVE	ENDOMETRIOSIS CAUSING HYSTERECTOMY-RESOLVED,INSOMNIA-ONGOING
	231120	ALLERGIC	SEASONAL ALLERGIES
		GASTROINTESTINAL	EPISODIC CONSTIPATION
		HEENT/MOUTH	TMJ SURGERY, DEVIATED SEPTUM SURGERY FARSIGHTED CLEAR RHINORRHEA, POST NASAL DRIP SINUS HEADACHES
		MUSCULOSKELETAL	DISCECTOMY L5-S1
		NEUROLOGIC	HEADACHES
		REPRODUCTIVE	HYSTERECTOMY AND BILATERAL OOPHORECTOMY
	231139	ALLERGIC	CEDAR

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Inv. Name	Patient Number	Body System	Description
Croft	231139	DERMATOLOGIC	ACNE
		HEENT/MOUTH	CLEAR RHINORRHEA
		NEUROLOGIC	HEADACHES
Delgado	41069	ALLERGIC	SEASONAL ALLERGIES NKDA
		GYNECOLOGICAL	TUBAL 5 YEARS AGO
		HEENT/MOUTH	SEASONAL ALLERGIES FOR PAST >5YRS, COLD SORES WITH SINUS HEADACHES 10/10/00
	41070	ALLERGIC	ENVIRONMENTAL
		CARDIOVASCULAR	OCCASIONAL PALPITATIONS VARICOSE VEINS
		DERMATOLOGIC	BASAL CELL LESIONS - ONE RGT ARM AND ONE FACE - REMOVED 1997-1998 PSORIASIS
		GASTROINTESTINAL	ACID REFLUX; CHOLECYSTECTOMY 1993
		HEENT/MOUTH	TOSILLECTOMY 1959; ADIE'S PUPIL(LFT); MIGRAINE HEADACHES (SINCE 98 10) HEADACHES SINCE 9-99, OCCASIONAL TINNITUS
		METABOLIC/ENDOCRINE	HYSTERECTOMY (PARTIAL) 1988; OBESITY HYPOTHYROID

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Medical History Descriptions - Listing by Patient
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Inv. Name	Patient Number	Body System	Description
Delgado	41070	MUSCULOSKELETAL	MYDOGRAM 1973 CHRONIC BACK PAIN; CARPAL TUNNEL-RGT ARM; CHRONIC LFT HIP PAIN (ARTHRITIS); ARTHRITIS-OSTEO, STIFF NECK
		PULMONARY	OCCASIONAL BRONCHITIS SHORTNESS OF BREATH WITH PHYSICAL EXERTION
		RENAL/URINARY TRACT	INCREASE URINARY FREQUENCY AT NIGHT X6 YRS, RECURRENT UTI'S
	41093	ALLERGIC	ENVIRONMENTAL ALLERGIES
		DERMATOLOGIC	MILD ROSACEA BRIDGE OF NOSE "ONGOING", ACNE FACE AND BACK AREA
		GASTROINTESTINAL	DIARRHEA - MILD; HEARTBURN - MILD, OCCASIONAL CONSTIPATION & GASTRIC IRRITATION
		HEENT/MOUTH	PIECE OF METAL REMOVED FROM EYE 1959, TONSILLECTOMY 1949
		MUSCULOSKELETAL	PT. STATES CHRONIC BACK PAIN SINCE 1990, LEFT ANKLE FX 2 YRS AGO, INTERMITTENT LEG CRAMPS
		NEUROLOGIC	MIGRAINES 2X/MONTH ALL HER LIFE, HX OF NON-MAGRAINE H/A, SPORADIC SLEEPING PATTERN SINCE 1997/ CONCUSSION 1965 THROWN FROM A HORSE
		PULMONARY	SOB WITH EXERTION "ONGOING" PT STATES HX OF ASTHMA ENTIRE LIFE CURRENTLY NOT TREATED
		WEIGHT	GAINED 30 LBS, IN PAST YEAR
	41094	ALLERGIC	ALLERGIES TO POLLEN, STRAWBERRIES, COFFEE, CAT HAIR, GRASS; ALLERGY SHOTS AS TEENAGER/CHILD

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Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Delgado	41094	CARDIOVASCULAR	RIGHT BUNDLE BRANCH BLOCK SINCE 1995
		GASTROINTESTINAL	HERNIA REPAIR IN 1962
		MISC. SURGERIES	HYSTERECTOMY 1992, PLASTIC SURGERY 1998, BREAST REDUCTION 1968
		NEUROLOGIC	MIGRAINE H/A'S X10 YRS
DuBoff	311017	DERMATOLOGIC	DRY SKIN ON FACE 1981-PRESENT
		GASTROINTESTINAL	HIATAL HERNIA 1993-PRESENT
		HEENT/MOUTH	MYOPIA 1952-PRESENT
		MUSCULOSKELETAL	FRACTURED LEFT ANKLE SURGERY TO INSERT PIN IN 1997;LAMINECTOMY LUMBAR VERTEBRA 4 IN 1976 AND LUMBAR VERTEBRA 5 IN 1994;AMPUTATED METATARSAL 1,2&3 1972
		NEUROLOGIC	HERPES ZOSTER 8/99-PRESENT
		PULMONARY	ASTHMA 1945-PRESENT
	311018	DERMATOLOGIC	FACIAL ACNE SINCE 1983
		GASTROINTESTINAL	IRRITABLE BOWEL SYNDROME 1986-1996; ANAL FISSURE SINCE 1991
		HEENT/MOUTH	MYOPIA SINCE 1980

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Inv. Name	Patient Number	Body System	Description
DuBoff	311018	NEUROLOGIC	MIGRAINE HEADACHES SINCE 1996
		PULMONARY	BRONCHITIS 1995 AND 1997
		RENAL/URINARY TRACT	YEAST INFECTIONS SINCE 1984, LAST 9/-/99
		SURGERY	APPENDECTOMY 1991
	311115	DERMATOLOGIC	PSORIASIS (SCALE) 1983-PRESENT
		GASTROINTESTINAL	INDIGESTION 1979-PRESENT;GASTRITIS 1994
		HEENT/MOUTH	TENSION HEADACHES 1985-PRESENT;MYOPIA 1992-PRESENT;HAYFEVER 1975-PRESENT
		MUSCULOSKELETAL	BUNIONECTOMY LEFT FOOT 1996
		RENAL/URINARY TRACT	YEAST INFECTION 1996-1999;URINARY TRACT INFECTION 1999
	311116	ALLERGIC	MORPHINE 1987-PRESENT
		GASTROINTESTINAL	INTESTINAL GROWTH (BENIGN) 1955; CHOLECYSTECTOMY WITH LITHIASIS 1990
		GYNECOLOGICAL	TOTAL HYSTERECTOMY 1990; ECTOPIC PREGNANCY 1985; CESARIAN SECTION'S 1978,1979,1987,1989,1990, BILATERAL BREAST IMPLANTS 1985;LAPAROSCOPY 1985
		HEENT/MOUTH	SINUS CONGESTION 1970-PRESENT;TENSION HEADACHES 1970-PRESENT;PRESBYOPIA 1989-PRESENT

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Inv. Name	Patient Number	Body System	Description
DuBoff	311116	METABOLIC/ENDOCRINE	PARTIAL THYROIDECTOMY (BENIGN NODULE) 1985
		NEUROLOGIC	MIGRAINE HEADACHES 1998-PRESENT
Dunner	211040	ALLERGIC	PLN
		MIGRAINE	AGE 27 TO PRESENT
	211109	ALLERGIC	CODEINE (97)
		MUSCULOSKELETAL	KNEE OPERATION 1983
	211110	CARDIOVASCULAR	HYPERTENSION 1990-PRESENT
		GASTROINTESTINAL	APPENDECTOMY 1997; APPENDICITIS DAY OF SURGERY
		METABOLIC/ENDOCRINE	POST-MENOPAUSE 1965 START DATE 1996 (ONGOING)
		MUSCULOSKELETAL	APRIL 1991 FELL ON KNEE CHONDROMYELITIS (ONGOING)
		RENAL/URINARY TRACT	TUBAL LIGATION 1985 FOR BIRTH CONTROL
	211145	METABOLIC/ENDOCRINE	INCREASED TRIGLYCERIDE/CHOLESTEROL SINCE 10/98 ONGOING
		NEUROLOGIC	HEADACHES, INTERMITTENT SINCE 1/12/00 MILD ONGOING

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Inv. Name	Patient Number	Body System	Description
Dunner	211146	ALLERGIC	1964 ERYTHROMYCIN ALLERGY REACTION WAS MOUTH SORE & STOMACH CRAMPS (RESOLVED)
		DERMATOLOGIC	MASTECTOMY 1979- NON-CANCEROUS TUMOR (RESOLVED)
		HEENT/MOUTH	DEVIATED NASAL SEPTUM-1998 ONGOING (RESOLVED)
		PULMONARY	ASTHMA AT CHILD (RESOLVED)
	211147	ALLERGIC	HAY FEVER 1984-PRESENT
		RENAL/URINARY TRACT	TUBAL LIGATION 1997; OVARY REMOVAL 1996
Fava	51141	ALLERGIC	ERYTHROMYCIN, SULFUR
	51142	RENAL/URINARY TRACT	FREQUENT URINARY TRACT INFECTIONS
Ferguson	241031	ALLERGIC	HOUSEHOLD ALLERGIES
		CARDIOVASCULAR	MINOR ATRIAL FLUTTER-1993; HIGH BLOOD PRESSURE-1993; HEART PALPITATION-1993
		GASTROINTESTINAL	APPENDECTOMY-1950
		HEENT/MOUTH	MILD TENSION HEADACHES-1944
	241032	DERMATOLOGIC	HIVES-1990-NOT CURRENT

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Inv. Name	Patient Number	Body System	Description
Ferguson	241032	GASTROINTESTINAL	GAS-W/USE OF PROZAC - 1991(CONTINUING)
		MUSCULOSKELETAL	EDEMA IN HANDS AND FEET SINCE 01-01-96(CONTINUING)
		NEUROLOGIC	SEVERE MIGRAINE HEADACHES 1XYEAR SINCE 1990 (CONTINUING); MODERATE TENSION HEADACHES 1XWK SINCE 1998(CONTINUING)
		SURGERY	TONSILLECTOMY-1982 MAMOPLASTY-1998 HYSTERECTOMY-1985 OOPHORECTOMY-1997
	241073	DERMATOLOGIC	ECZEMA 1997
		GASTROINTESTINAL	DIARRHEA 8-1999
		GENITILIA	IRREGULAR PERIODS SINCE 1986
		HEENT/MOUTH	NEARSIGHTED 1980, SLIGHT HEARING LOSS IN BOTH EARS 1989
		NEUROLOGIC	BALANCE PROBLEMS 1973 (RARELY) HEADACHES 1984,MIGRAINES 1984, CONCUSSION 1984
	241074	ALLERGIC	ALLERGIES 1998
		DERMATOLOGIC	ACNE 05/1999
		GASTROINTESTINAL	COLONOSCOPY 05-1999, 10-1999 ENDOSCOPY 01-2000
		GENITALIA	YEAST INFECTIONS 1988 CRAMPS 1988

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Inv. Name	Patient Number	Body System	Description
Ferguson	241074	HEENT/MOUTH	HEADACHES 07/1999, MIGRAINES 07/1999, NEAR SIGHTED 05/1999 (WEAR GLASSES)
		MUSCULOSKELETAL	CRACKED TAIL BONE 02-1990
		RENAL/URINARY TRACT	DIARRHEA 1998, CONSTIPATION 1998 HEMORRHOIDS 01/2000, IRRITABLE BOWEL 01-2000, URINARY TRACT INFECTION 12/1999
Gilmer	61081	ALLERGIC	DUST, MOLD, GRASSES
		CIRCULATORY	RAYNAUD'S DISEASE
		MUSCULOSKELETAL	R KNEE PAIN
	61082	ALLERGIC	SEASONAL RHINITIS (1980-PRESENT)
		GASTROINTESTINAL	ACID REFLUX(1998-PRESENT)
		HYSTERECTOMY	1985,COMPLETE
		MUSCULOSKELETAL	BACK PAIN (12/99-PRESENT)
Halbreich	71077	CARDIOVASCULAR	HYPERTENSION SINSE -/-/89
		MUSCULOSKELETAL	ARTHRITIS SINCE -/-/96 (R) ANKLE INJURY/SURGERY-/-/95, (R) THUMB SURGERY -/-/99,(L) THUMB SURGERY -/-/98

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Inv. Name	Patient Number	Body System	Description
Halbreich	71077	NEUROLOGIC	VASCULAR HEADACHES 1/97
Helfing	81003	ALLERGIC	SEASONAL ALLERGIES START APPROX 1956; PENICILLIN ALLERGY 1982-WELLS ALL OVER BODY
		GASTROINTESTINAL	ULCERS 1997; COLITIS 1950; GALLSTONES 1954; DIVERTICULITIS 1993; HEMMORRHOIDS 1955; POLYPS REMOVED 1995 AND 1997 FROM COLON
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM SINCE 1984 TO PRESENT (STABLE ON MEDS)
		MUSCULOSKELETAL	ARTHRITIS 1989 TO PRESENT
		NEUROLOGIC	MIGRAINE HEADACHE 1979; TENSION HEADACHES SINCE MARCH 1999 TO PRESENT, LATE ENTRY: TENSION HEADACHES ARE MILD
	81004	ALLERGIC	ERYTHROMYCIN SINCE 1984-SKIN RASH; BEE STINGS-1996 ON HAND AND ARM, GOT PURPLE; ALLERGIES CONT.
		CARDIOVASCULAR	MITRAL VALVE PROLAPSE SINCE 1987 TO PRESENT
		MUSCULOSKELETAL	FRACTURE TO ARM WITH SLIGHT WEAKNESS
	81051	ALLERGIC	CODEINE SINCE 1990-ITCHING EXCESSIVELY; MEFOXIN SINCE 1993-ANAPHYLACTIC SHOCK; OPIATES SINCE 1974-CONVULSIONS
		DERMATOLOGIC	ECZEMA SECONDARY TO IBS
		GASTROINTESTINAL	IRRITABLE BOWEL SYNDROME SINCE 1979; HEMORRHOIDS SINCE 1984, ULCERATIVE COLITIS SINCE 1979

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Inv. Name	Patient Number	Body System	Description
Helfing	81051	MUSCULOSKELETAL	LOW BACK PAIN
	81052	ALLERGIC	CODEINE-REACTION UNKNOWN DATE-ONGOING
		GASTROINTESTINAL	ULCERS SINCE 1975-RESOLVED
		HEMATOLOGIC	HEPATITIS C SINCE APRIL 1998 IN REMISSION -ONGOING
		MUSCULOSKELETAL	LOW BACK PAIN-DATE UNKNOWN-ONGOING
		NEUROLOGIC	TENSION HEADACHE DAILY 1999-ONGOING
		REPRODUCTIVE	OVARIAN CYST 1995-RESOLVED
	81075	ALLERGIC	DEMEROL (VOMITTING, DIZZINESS) START 1986-ONGOING; SEASONAL HAYFEVER -START 1974-ONGOING
		CARDIOVASCULAR	HIGH BLOOD PRESSURE DURING PREGNANCY STOP 03/19/99
		METABOLIC/ENDOCRINE	OBESITY-START DATE UNKNOWN-ONGOING, HYPOTHYROIDISM STOP 1987
		NEUROLOGIC	MIGRAINE HEADACHES - ONCE A MONTH -START 1986-ONGOING; CONCUSSION 1982-NO SEQUELAE-RESOLVED
		REPRODUCTIVE	1985 PARTIAL REMOVAL OF OVARY AND FIBROID TUMORS-RESOLVED 1974
	81076	ALLERGIC	SEASONAL ALLERGIES, HAYFEVER START APPROX 1994 - ONGOING

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Inv. Name	Patient Number	Body System	Description
Helfing	81076	CARDIOVASCULAR	HEART MURMUR-CHILDHOOD - EXACT START UNKNOWN - ONGOING
		GYNECOLOGICAL	INCOMPETENT CERVIX START APRIL 96 TO PRESENT
		METABOLIC/ENDOCRINE	NIDDM -JUNE 99 TO PRESENT BUT CONTROLLED
		PULMONARY	ASTHMA-INFANCY TO PRESENT
	81103	ALLERGIC	SEASONAL ALLERGIES (NASAL DRIP, RUNNY NOSE) SINCE 1970-ONGING
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM SINCE 1979 - ONGOING; POST MENOPAUSAL SINCE 1985
		MUSCULOSKELETAL	NECK INJURY IN MVA 1/7/97 - ONGOING
		REPRODUCTIVE	HYSTERECTOMY 1985 DUE TO POSSIBLE ENDOMETRIOSIS
Hoopes	271021	ALLERGIC	ALLERGY TO BEES SINCE CHILDHOOD CAUSES DIFFICULTY BREATHING ONGOING; ALLERGY TO MANGOS SINCE 1995 CAUSES EXTREME HIVES-ONGOING
		CARDIOVASCULAR	H/O HEART MURMUR-1989-CONTINUING
		INFECTIOUS DISEASE	RHEUMATIC FEVER-1989 RESOLVED
		MUSCULOSKELETAL	FRACTURED L FEMUR 1997 RESOLVED, FRACTURED R FEMUR 1998 RESOLVED
	271022	ALLERGIC	SEASONAL ALLERGIES 1984

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Medical History Descriptions - Listing by Patient
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Inv. Name	Patient Number	Body System	Description
Hoopes	271022	GENITO-URINARY	TUBAL LIGATION-1993; MENSTRUAL CRAMPS-1992 ALSO BLOATING BEFORE MENTRUAL PERIOD SINCE 1992
		HEENT/MOUTH	DEVIATED SEPTUM 1988
		HEMATOLOGIC	ANEMIA 1956
		NEUROLOGIC	HEADACHES 1991
		RENAL/URINARY TRACT	HISTORY OF HEMMORHOIDS 1989
	271045	ALLERGIC	SEASONAL ALLERGIES-1997
Liebowitz	91005	ALLERGIC	MUSHROOMS, CHOCOLATE, STRAWBERRIES, POLLEN, CATS
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM
	91006	NEUROLOGIC	AUTO ACCIDENT 1982-SKULL FRACTURE;UNCONSCIOUS FOR SEVERAL HRS;MAY HAVE HAD 1 SEIZURE-NO NEUROLOGICAL SEQUELAE FROM THAT-HAS BEEN CLEARED NEUROLOGICALL
	91035	VERICOSE VEINS	SURGERY 30 YEARS AGO
	91036	MUSCULOSKELETAL	R SHOULDER SURGERY 9/98
	91097	ALLERGIC	HAY FEVER, SEASONAL ALLERGIES
		GASTROINTESTINAL	CONSTIPATION

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Inv. Name	Patient Number	Body System	Description
Liebowitz	91097	GYNECOLOGIC	S/P TUBAL LIGATION 1990
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM DX 1990
		NEUROLOGIC	SEDATION, FATIGUE
	91098	ALLERGIC	ALLERGY TO SULFA MEDICATIONS
		HEENT/MOUTH	RECONSTRUCTIVE RHINOPLASTY - 1995
	91137	DERMATOLOGIC	REMOVAL EXCESS SKIN FROM ABNORMAL SURFACE 1998
		GASTROINTESTINAL	GASTRIC STAPLING 1996 FOR OBESITY
		SKIN	BENIGN GROWTH REMOVED FROM NECK 1998
	91138	NEUROLOGIC	MIGRAINES
		SKIN	RECENT LASER TREATMENT FOR ACNE BLEMISHES.
Londborg	101009	ALLERGIC	HAYFEVER ONGOING/SEASONAL
		CARDIOVASCULAR	HYPERTENSION WITH LAST THREE WEEKS OF PREGNANCY ONSET 1978-RESOLVED 1979
		HEENT/MOUTH	ALLERGIC RHINITIS ONGOING

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Inv. Name	Patient Number	Body System	Description
Londborg	101009	METABOLIC/ENDOCRINE	GESTATIONAL DIABETES 1990, RESOLVED
		NEUROLOGIC	CHRONIC HEADACHES BEFORE PERIOD, ONGOING STABLE
	101010	CARDIOVASCULAR	CORONARY ARTERY BYPASS 6/97 RESOLVED
		HEMATOLOGIC	ANEMIA AT AGE 16. TOOK FE SUPPLEMENT 1 YR ONSET 1963-RESOLVED
		METABOLIC/ENDOCRINE	"HIGH NORMAL" THYROID LEVEL 6-7 YRS AGO
		MUSCULOSKELETAL	ACHE & PAINS NON-SPECIFIC ONSET UNKNOWN - ONGOING
		REPRODUCTIVE	1979 TUBAL LIGATION RESOLVED
	101043	ALLERGIC	ALLERGIES TO POLLEN & ANIMAL DANDER ONSET 1977 ONGOING REACTION-HIVES
		DERMATOLOGIC	CYSTIC ACNE ON FACE, CHEST, & BACK ONSET 1979 ONGOING
		MUSCULOSKELETAL	FIBROMYALGIA ONSET 1977 ONGOING
	101044	ALLERGIC	LACTOSE INTOLERANCE 1980 ONGOING, NASAL CONGESTION FROM POSSIBLE ALLERGIES, ONSET 1984/ONGOING
		DERMATOLOGIC	MILD ACNE ONSET 1969/ONGOING
		GASTROINTESTINAL	IRRITABLE BOWEL SYNDROME ONSET 1985/ONGOING

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Inv. Name	Patient Number	Body System	Description
Londborg	101044	MUSCULOSKELETAL	HERNIATED DISC SECONDARY TO MVA 2/24/99,8/15/99, ASSOCIATED PAIN IN LOW BACK, NECK AND LEGS ONGOING
		NEUROLOGIC	HEADACHES ONGOING ONSET UNKNOWN MILD INTENSITY, DEPRESSION RELATED INSOMNIA ONSET UNKNOWN - ONGOING MILD INTENSITY
		RENAL/URINARY TRACT	FREQUENT VAGINAL YEAST INFECTION ONSET 1980 ONGOING
		REPRODUCTIVE	DYSMENORRHEA ONSET 1976/ONGOING
Lydiard	221033	DENTAL	BRUXISM BEGAN 1995-CONT(ONGOING)
	221034	SURGERY	BREAST IMPLANT 1988; TUBAL LIGATION 1986
	221130	FIBRO MYALGIA	DIAGNOSED 1998
		MUSCULOSKELETAL	HEADACHES-ONGOING
McGrath	111171	ALLERGIC	SEASONAL ALLERGY, ? PCN ALLERGY
		CARDIOVASCULAR	FUNCTIONAL HEART MURMUR, HYPERTENSION
		DERMATOLOGIC	CONGENITAL FACE LESION
		GASTROINTESTINAL	DIVERTICULITIS

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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Inv. Name	Patient Number	Body System	Description
McGrath	111171	METABOLIC/ENDOCRINE	OBESITY
		SKIN	SCALP SEBORRHEA
Moreines	121007	CARDIOVASCULAR	MITRAL VALVE PROLAPSE-ONGOING
		GYN	CONE BIOPSY CERVIX 1995-NEGATIVE-RESOLVED
		HEENT/MOUTH	SINUS INFECTIONS 1985-1991 CURRENTLY RESOLVED
		NEUROLOGIC	HEADACHES 1975-CURRENTLY 19.2 WEEKS-ONGOING
		RENAL/URINARY TRACT	URINARY TRACT INFECTION 1984-1995-RESOLVED
Munjack	131011	CARDIOVASCULAR	HYPERCHOLESTEROLEMIA-1994, CT FOLLOWED AND CONTROLLED
		DERMATOLOGIC	SKIN CANCER-L UPPER ARM, EXCISION IN 1995, RESOLVED, NO SEQUELAE
		GASTROINTESTINAL	ANAL FISTULA-1999, OPERATED, RESOLVED; HEMORRHOIDS-1994-CT, MODERATE, TX C OTC MEDS
		HEENT/MOUTH	RECONSTRUCTIVE SURGERY-L EAR 1946; MYOPIA, 1952, PT WEARS CONTACT LENSES
		LYMPHATIC	TONSILLECCTOMY-CHILDHOOD, NO SEQUELAE
		METABOLIC/ENDOCRINE	"THYROID PROBLEMS"-PT UNAWARE OF DIAGNOSIS, 1950-1952, RESOLVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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Inv. Name	Patient Number	Body System	Description
Munjack	131011	MUSCULOSKELETAL	BONE TUMORS R KNEE-REMOVED 1989, NO SEQUAELEA
		NEUROLOGIC	TENSION HEADACHES-1989, CT, OTC MEDS; MIGRAINE HEADACHES, 1950-1950, RESOLVED; TRIGEMINAL NEURALGIA-1982-1983, RESOLVED
		PULMONARY	CHRONIC SINUSITIS-1996-CT, 3-4X/YEAR, MODERATE
	131012	HEENT/MOUTH	CHRONIC SINUSITIS, 1979-CT, MILD-MOD, OTC MED HYPEROPIA-1992
		MUSCULOSKELETAL	LOWER BACK PAIN - 1994-CT, MOD
		NEUROLOGIC	TENSION HEADACHES -1979-CT, ABOUT 5-6 MONTHS, OTC MED,MIGRAINE HEADACHE - 1979, 1 MONTH, MOD
		SURGERY	BREAST AUGMENTATION - 1989
	131071	DERMATOLOGIC	TATOO (L) ANTERIOR CHEST (PE FINDINGS)
		MUSCULOSKELETAL	BROKEN FEMUR -1991 DISLOCATED 5TH FINGER (R) HAND 1991
		NEUROLOGIC	MIGRAINE HEADACHES-SEPTEMBER'99
	131072	HEENT/MOUTH	EARACHES CHILDHOOD-OCTOBER '99, NO TX-SECONDARY TO CONGENITALLY SMALL,EUSTACHIAN TUBES; HYPEROPIA-SINCE 1958, RX GLASSES
		MUSCULOSKELETAL	BACK PAIN- MOD-SEV DUE TO L2 AND L3 FUSION, INTERMITTENT, CT

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Inv. Name	Patient Number	Body System	Description
Munjack	131072	NEUROLOGIC	TENSION HEADACHES- MOD-SEV. SINCE 1997, CT
		PULMONARY	ASTHMA BRONCHIALE-1992,CT; PNEUMONIA-12'92-04'98, RESOLVED
		SURGERY	TONSILLECTOMY 1946 BILATERAL EUSTACHIAN TUBES INSERTS-1980
	131125	1) SURGERY; 2) CHICKEN POX; 3) MENSTRUAL CRAMPS	1)-(L) BREAST BIOPSY-MARCH 1998 BENIGN RESOLVED 2)-CHICKEN POX 1998, RESOLVED; 3)-MENSTRUAL CRAMPS SINCE 1998, MILD-MOD
		ALLERGIC	PENICILLIN, ASPIRIN, SPIDER BITES; SEASONAL-POLLENS, GRASS-HAYFEVER SINUS CONGESTION SINCE 1990
		CARDIOVASCULAR	HEART MURMUR SEPT 1998, HYPERTENSION SEPT 1999 CONTROLLED & FOLLOWED
		DERMATOLOGIC	IMPETIGO-1967
		HEENT/MOUTH	MYOPIA-1980, WEARS GLASSES,CONTINUING
		HEMATOLOGIC	IRON DEFICIENCY ANEMIA-OCT 1999 RESOLVED
		NEUROLOGIC	HEADACHES, MILD 1990 CT
	131126	ALLERGIC	CAT DANDER-SINUS CONGESTIONS, -1999 CONJUNCTIVITIS
		HEENT/MOUTH	MYOPIA - 1969
		MUSCULOSKELETAL	BROKEN (L) ANKLE -1980

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Inv. Name	Patient Number	Body System	Description
Munjack	131126	SURGERY	RECONSTRUCTIVE SURGERY - 1980 - (L) ANKLE
	131143	GASTROINTESTINAL	HEMORRHOIDS-1998, CT
		HEMATOLOGIC	IRON DEFFICIENCY ANEMIA - MAY 1999
		MUSCULOSKELETAL	UPPER BACK PAIN - 1982, CT KYPHOSCOLIOSIS - 1982, CT
		NEUROLOGIC	TENSION HEADACHES 1989, CT
		RENAL/URINARY TRACT	UTI-RECURRENT, 1979
		SURGERY	(R) KNEE-DIAGNOSTIC PROCEDURE 1972
	131144	ALLERGIC	POLLENS- SINUS CONGESTION
		HEENT/MOUTH	STRABISMUS CT MYOPIA, SINCE BIRTH, CORRECTIVE LENSES,CT
		MUSCULOSKELETAL	LOWER BACK PAIN-1989, MILD,CT
		PULMONARY	ASTHMA BRONCHIALE SINCE CHILDHOOD,NO TX VERY MILD
		SURGERY	(L)EYE MUSCLE RELAXATION-1983 & 1995, NO SEQUELAE.
Nelson	141041	CARDIOVASCULAR	HYPERCHOLESTEROLEMIA, HTN - BOTH CONTROLLED

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Inv. Name	Patient Number	Body System	Description
Nelson	141041	NEUROLOGIC	DECREASE MEMORY OF CONCENTRATION-MILD CHRONIC
		RENAL/URINARY TRACT	INCONTINENCE, URINARY FREQ, INCREASE THIRST
Oldroyd	321055	ALLERGIC	PENICILLIN 1978 -ONGOING
		CARDIOVASCULAR	HYPERTENSION 1995-1997; HYPERCHOLESTEROLEMIA 1995 1997
		DERMATOLOGIC	LACERATION, FOREHEAD 1968; CHIN LACERATION 1989
		GASTROINTESTINAL	GASTROINTESTINAL REFLUX DISORDER 1998-ONGOING
		GENITAL	VENEREAL DISEASE 1978-1978
	321056	DERMATOLOGIC	1957 BURN, LEFT FOREARM
		GASTROINTESTINAL	HYPERCHOLESTEROLEMIA, 1983
		METABOLIC/ENDOCRINE	HYPOTHYROID, 1993
	321087	ALC ABUSE/DEPEND; MARIJUANA ABUSE/DEPEND; GONNORHEA	1964-1/95; 1968-7/95; 1968 ONLY
		CARDIOVASCULAR	MILD HYPERTENSION 10/25/99-NCS; RIGHT BUNDLE BRANCH BLOCK, LEFT ATRIAL FASICULAR BLOCK, BRADYCARDIA - NCS

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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Inv. Name	Patient Number	Body System	Description
Oldroyd	321087	DERMATOLOGIC	CYST, NECK (BENIGN) - CYST SURGICALLY REMOVED 1989
		GASTROINTESTINAL	APPENDICITIS 1950; TONSILLITIS 1951; ULCER 1989-1995; APPENDECTOMY 1950; TONSILLECTOMY 1951; INDIGESTION 1994-PRESENT
		HEENT/MOUTH	HEARING LOSS LEFT 1985-PRESENT; GLAUCOMA BILATERAL 8/99-PRESENT; DEVIATED SEPTUM 1997; UVULA UPPP 1997
		METABOLIC/ENDOCRINE	INFECTIONS HEPATITIS 1968-1969
		MUSCULOSKELETAL	OCCASIONAL BILAT MILD LEG CRAMPS 1990;L SHOULDER DISLOCATION 1966;OSTEOARTHRITIS L SHOULDER 1995-ONGOING;L SHOULDER SURGERY DISLOCATION REDUCTION 1966
Prover	261023	ALLERGIC	CAT DANDER, PENICILLIN
		DERMATOLOGIC	ECZEMA 1994-ONG
		GASTROINTESTINAL	ULCER 1981 RESOLVED
		HEENT/MOUTH	TONSILLECTOMY 1973; MYOPIA 1993-ONG
		MUSCULOSKELETAL	CHRONIC TENDONITIS 1995-ONG
		NEUROLOGIC	CARPAL TUNNEL SYND 1995-ONG; TENSION HEADACHES 1996-1998
		PULMONARY	URI I TIME/YEAR 1989-ONG; ASTHMA 1995-ONG; BRONCHITIS 1981-ONG

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Inv. Name	Patient Number	Body System	Description
Prover	261023	RENAL/URINARY TRACT	UTI'S (3 EPISODES) 1992-ONG
Rapaport	151037	ALLERGIC	CODEINE-GI DISTRESS
		CARDIOVASCULAR	HYPERTENSION (1992)
		DERMATOLOGIC	INTERMITTENT RASH IN LEFT UNDERARM, STARTED IN 1996
		GASTROINTESTINAL	S/P CHOLECYSTECTOMY (1970)
		HEMATOLOGIC	INCREASED BLOOD PROTEIN-CURRENT (1999)
		HYSTERECTOMY	S/P TAHBSO (1994)-DUE TO FALSE DIAGNOSIS OF UTERINE CANCER
		MUSCULOSKELETAL	ARTHRITIS (1994) KNEES/ARM/NECK
		NEUROLOGIC	BILATERAL HEARING LOSS
		PULMONARY	PNEUMONIA (1940)
		RENAL/URINARY TRACT	INTERMITTENT ABDOMINAL PAIN SINCE 1990
	151038	ARTHRITIS	AFFECTS KNEES-BILATERAL-CLINICALLY STABLE >5YRS-TAKES MOTRIN PRN
		CARDIOVASCULAR	RX ZOCAR; HYPERCHOLESTEROLEMIA-CLINICALLY STABLE >1YR

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Inv. Name	Patient Number	Body System	Description
Rapaport	151038	GASTROINTESTINAL	RX ZANTAC; 1)BLADDER SCAR-1998-UNKNOWN CAUSE 2)2 EPISODES HEMATURIA-UNKNOWN DATE.IRRITABLE BOWEL SYNDROME-CLINICALLY STABLE >2YRS
		MUSCULOSKELETAL	HX R ELBOW FX-CURRENTLY STABLE-RESOLVED 10/83
		RENAL/URINARY TRACT	TVAP-LAZER MARCH '98-CURRENTLY STABLE; BLADDER CA-CA 0 MALIGNANCY SURGERY-AUG 8'99 ; F/U AT 3 MTHS
	151085	CARDIOVASCULAR	1995 HX OF BENIGN CARDIAC MURMUR CONTINUOUS SINCE CHILDHOOD
		MUSCULOSKELETAL	1990 CONTINUOUS (TAKES ALLEVE PR) MUSCULOSKELETAL BACK PAIN
	151086	ALLERGIC	MORPHINE/NICKEL
		DERMATOLOGIC	RASH ON R ELBOW 1996, ACTIVE 6/11/96
		GASTROINTESTINAL	GERD '98; ZANTAC 150 MG PO QAM ACTIVE
		HEENT/MOUTH	FARSIGHTED-AGE 3-PRESENT TONSILLECTOMY-DATE UNKNOWN
		METABOLIC/ENDOCRINE	PERIMENOPAUSAL-PROGESTERONE/ESTROGEN-BEGAN '98
		MUSCULOSKELETAL	FIBROMYALGIA-TX WITH PROZAC, 1973-LUMP IN BREAST REMOVED, KNEE SURGERY-DATE UNKNOWN, CARPAL TUNNEL SYNDROME (UNKNOWN ONSET)
		NEUROLOGIC	MIGRAINES-ONSET 5/99

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Inv. Name	Patient Number	Body System	Description
Rapaport	151086	PULMONARY	BRONCHITIS 10/14/99-PRESENT ACTIVE; TX ZITHROMAX; - PNEUMONIA IN 1979
		RENAL/URINARY TRACT	1996-OVARY REMOVED
	151095	ALLERGIC	SINUS CONGESTION/ALLERGY- UNKNOWN START DATE
		GASTROINTESTINAL	S/P B HERNIA REPAIR 1969-1976, APPENDECTOMY 1968, HERNIA SURGERY IN 1976
		HEMATOLOGIC	HYPERCHOLESTEROLEMIA - RX ZOCAR-DATES UNKNOWN
		MUSCULOSKELETAL	L KNEE S/P ARTHROSCOPY (4 SURGERIES); 1989-1994 -STILL OCCASSIONAL PAIN L KNEE -PRESCRIPTION - TAKES IBUPROFEN PRN
	151096	GASTROINTESTINAL	APPENDICITIS W/ APPENDECTOMY (1981-1987), BENIGN PROSTATE HYPERPLASIA-DATE UNKNOWN, APPENDECTOMY IN 1987
		HEENT/MOUTH	GLAUCOMA STABLE ON: TIMOLOL, TRUSOPT, XALATAN(START: 1996-PRESENT)
		MUSCULOSKELETAL	MUSCULOSKELETAL - LOWER BACK PAIN L1-L5; RX-TYLENOL & IBUPROFEN
		PULMONARY	VIRAL PNEUMONIA (1966-1968)
	151099	ALLERGIC	PENICILLIN - E-MYCIN 1979
		GASTROINTESTINAL	SLOW GASTRIC TRANSIT/EMPTYING 1955, 1954-RUPTED APPENDIX

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Inv. Name	Patient Number	Body System	Description
Rapaport	151099	HEENT/MOUTH	MYOPIA 1960
		HEMATOLOGIC	BORDERLINE ANEMIA 1988-PRESENT; 1949 SCARLET FEVER
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM 1957 - RESOLVED
		NEUROLOGIC	MIGRAINES - START 1988 - CONTINUES
		PULMONARY	WHOOPING COUGH 1947; PLEURISY/PNEUMONIA 1963 OCCASIONAL LOW BLOOD PRESSURE-DATES UNKNOWN
		RENAL/URINARY TRACT	UTI - LAST TIME 1996
	151100	ALLERGIC	ALLERGIES, POLLEN: 3/92 -CURRENT
		CARDIOVASCULAR	HIGH CHOLESTEROL: 1/98-CURRENT
		GASTROINTESTINAL	LAPARESCOPY-DATE UNKNOWN
		HEENT/MOUTH	TONSILLECTOMY 1951;SINUS ALLERGIES: 3/92-CURRENT
		METABOLIC/ENDOCRINE	HYSTERECTOMY 3/83 - ENDOMETRIOSIS - 3/78-3/83
		PULMONARY	PNEUMONIA: 1/95-1/95
		RENAL/URINARY TRACT	RECURRENT BLADDER INFECTIONS, BLADDER SURGERY (COLPOPERINEOPLASTY) 7/21

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Inv. Name	Patient Number	Body System	Description
Rapaport	151118	MUSCULOSKELETAL	MUSCULOSKETAL PAIN START-94 STOP-CONTINUOUS, (R)/2 SHOULDER PRN IBUPROFEN
		NEUROLOGIC	TENSION HEADACHES - PRN IBUPROFEN
	151153	HEENT/MOUTH	L EYE PTOSIS MARCH 2000,SECONDARY LIGAMENT TEAR-UNKNOWN ETIOLOGY-CURRENTLY STABLE
		MUSCULOSKELETAL	L ANKLE FX 1999-CURRENTLY STABLE
Smith	281025	GASTROINTESTINAL	CROHNS DISEASE IN 1991-CHRONIC
		HEENT/MOUTH	TONSILECTOMY 1974; MYOPIA SINCE 1968-CHRONIC
		HEMATOLOGIC	ELEVATED CHOLESTEROL 1998
		PULMONARY	BRONCHITIS 1985
	281026	ALLERGIC	CODEINE, DESYREL, COMPAZINE, LIBRAX, BEER/HOPS, DUST, MOLD, MILDEW, ANIMALS
		CARDIOVASCULAR	FIRST DEGREE HEART BLOCK 1989 TO 1991
		GASTROINTESTINAL	CHOLYCYSTECTOMY 1980
		HEENT/MOUTH	MIGRAINE HEADACHES 1960; STIGMATISM 1960; TUBES IN EARS 1956 TO 1965
		HEMATOLOGIC	PLATELET DEFICIT 1958 TO 1963

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Inv. Name	Patient Number	Body System	Description
Smith	281026	MUSCULOSKELETAL	CHRONIC BACK PAIN, ARTHRITIS OF HAND, HIPS, BACK 1989
		PULMONARY	SEASONAL ASTHMA 1963
	281101	ALLERGIC	HAY 1967
		HEENT/MOUTH	TONSILECTOMY & ADENOIDECTOMY 1969
		HEMATOLOGIC	HEPATITIS A/B 1990
		MUSCULOSKELETAL	BACK PAIN SINCE 1998
		SURGERY	TUBAL LIGATION 1989
	281102	HEENT/MOUTH	NEARSIGHTED ASTIGMATISM 1962
		MUSCULOSKELETAL	LEG SPASMS 2/1999
		PULMONARY	POSITIVE TB TINE TEST 1967-1968
		UTERINE	IRREGULAR MENSTRATION 5/1999
	281107	GASTROINTESTINAL	COLON CANCER -1995-1996 TX W/2 INCHES OF COLON REMOVED; ACID REFLUX 1996-ONGOING; CHOLYCYSTITIS 1994-1994
		HEENT/MOUTH	CONTACTS/FAR SIGHTED 1979-ONGOING

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Inv. Name	Patient Number	Body System	Description
Smith	281107	HEMATOLOGIC	HYPERCHOLESTEROLEMIA 1997-ONGOING
		METABOLIC/ENDOCRINE	HYPOTHYROIDISM 1979-ONGOING
		MUSCULOSKELETAL	BUNIONECTOMY 1978
		NEUROLOGIC	INSOMNIA 11-99-ONGOING
		RENAL/URINARY TRACT	KIDNEY STONES TX W/ LITHOTRIPSY 1980-1980
		UTERINE	TOTAL ABDOMINAL HYSTERECTOMY 1975
	281108	BREAST UTERINE /INSOMNIA	FIBERCYSTIC BREASTS 1986-1986 BENIGN RIGHT BREAST TUMOR 1986-1986;HYSTERECTOMY SECONDARY TO FIBROIDS 1990; INSOMNIA 1996
		CARDIOVASCULAR	RHEUMATIC FEVER 1959-1960; HYPERTENSION 1994-ONGIONG; MURMUR 1959-ONGOING
		GASTROINTESTINAL	OCCASIONAL MILD SPASTIC COLON 1989-ONGOING; EXPLORATORY LAPAROTOMY 1998; CHOLECYSTITIS 1995; CHOLECYSTECOMY 1995
		HEENT/MOUTH	NEARSIGHTED 1984-CONTINUED
		MUSCULOSKELETAL	BACK PAIN 12-1-99 - ONGOING
Telew	171016	ALLERGIC	POSSIBLE PENICILLIN ALLERGY-1976-ONGOING

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Inv. Name	Patient Number	Body System	Description
Telew	171016	DERMATOLOGIC	DRY SKIN-FACIAL SINCE 1997-ONGOING
		GASTROINTESTINAL	APPENDECTOMY 1976-RESOLVED
		HEENT/MOUTH	TONSILLECTOMY 1973-RESOLVED
		NEUROLOGIC	TENSION HEADACHES SINCE 1996-ONGOING
	171027	ALLERGIC	SEASONAL ALLERIC RHINITIS-1967-ONGOING
		CARDIOVASCULAR	IRREGULAR HEART BEAT-RELATED TO AMITRYPTALINE USE-1997-RESOLVED
		GASTROINTESTINAL	ULCER-1960-ONGOING
		HEMATOLOGIC	ANEMIA-RELATED TO PREGNANCY-1980-RESOLVED
		METABOLIC/ENDOCRINE	POSTMENOPAUSAL SINCE 1997
		MUSCULOSKELETAL	BACK PAIN-MODERATE, OCCASIONAL-1998-ONGOING
		RENAL/URINARY TRACT	KIDNEY INFECTION-1971-RESOLVED, PELVIC INFLAMMATORY DISEASE-1984-RESOLVED, HEMORRHOIDS-1997-RESOLVED
Thase	181083	ALLERGIC	SENSITIVITY TO WOOL, SHELLFISH, PEANUTS.
		HEENT/MOUTH	ADENOIDECTOMY, S/P TONSILLECTOMY, AGE 6; S/P WIDSOM TEETH EXTRACTION, AGE 48

LIST3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Thase	181084	ALLERGIC	HAYFEVER LIKE SYMPTOMS
		HEENT/MOUTH	ASTIGMATISM; RIGHT ORBITAL PLASTIC SURGERY AFTER ASSAULT(HIGH SCHOOL)
		MUSCULOSKELETAL	S/P MULTIPLE RIB FRACTURES SECONDARY MVA(HIGH SCHOOL); MULTIPLE LIPOMAS APPEAR ON HIS FOREARMS, LOWER ABDOMEN & LOWER BACK
	181105	ALLERGIC	ZOLOFT-RASH, ERYTHROMYCIN-HIVES
		DERMATOLOGIC	ACNE ROSACEA
		GYNECOLOGICAL	DYSMENORRHEA SINCE AGE 13; S/P REMOVAL OF BENIGN CYST ON LEFT BREAST-AGE 21; FIBROCYSTIC BREASTS.
		HEENT/MOUTH	RECURRENT SINUSITIS
		MUSCULOSKELETAL	MILD DEGENERATIVE JOINT DISEASE IN LEFT KNEE; S/P FRACTURED LUMBAR VERTEBRAE-1993; CARPAL TUNNEL SYNDROME, BOTH WRISTS-DIAGNOSED 1998
	181106	ALLERGIC	PENICILLIN
		GASTROINTESTINAL	OCCASIONAL HEART BURN TREATED WITH OTC ACID REDUCERS
		HEMATOLOGIC	ANEMIA A FEW YEARS AGO. TREATED WITH IRON
		NEUROLOGIC	HEADACHES; APPROXIMATELY 1 PER WEEK FOR THE LAST THREE MONTHS

LIST3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Thase	181135	HEENT/MOUTH	HISTORY OF SINUS INFECTIONS; CHANGES IN NIGHT VISION
		NEUROLOGIC	HISTORY OF HEADACHES
		RENAL/URINARY TRACT	SUB-URETHRAL CYST DISCOVERED & REMOVED IN 1992
		REPRODUCTIVE	HISTORY OF MENSTRUAL CRAMPS
	181136	GASTROINTESTINAL	INDIGESTION & HEARTBURN
		HEENT/MOUTH	S/P WISDOM TEETH;S/P MASTOIDITIS & MYRINGOTOMY 4/99.SEV. INFECTION LED TO PLACEMENT OF MYRINGOTOMY TUBE R EAR SUB. INFECTIONS W/RESIDUAL HEARING LOSS
		MUSCULOSKELETAL	S/P MVA 1968-NO RESIDUAL EFFECTS, OCCASIONAL JOINT PAIN AND SORE MUSCLES
		RENAL/URINARY TRACT	NO UTI'S
		REPRODUCTIVE/BREAST	OOPHOROHYSTERECTOMY 1984/FIBROCYSTIC BREAST DISEASE 1980
Trivedi	191013	ALLERGIC	ZOLOFT-HIVES, 1996; SEASONAL ALLERGIES-1967; LITHIUM- PARANOIA/DELUSIONS, 1997
		CARDIOVASCULAR	SLIGHT HEART MURMUR-1977
		DERMATOLOGIC	OCCASIONAL ACNE-1991; IMPETIGO-1972
		HEMATOLOGIC	ANEMIA - 1973

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Trivedi	191013	MUSCULOSKELETAL	RT. LEG ARM PAIN 3/99 - ONGOING
		NEUROLOGIC	FREQUENT HEADACHES-1989 - ONGOING REAR SIGNTEDNESS - 1970 - ONGOING
		PULMONARY	ASTHMA - 1995 - ONGOING
		RENAL/URINARY TRACT	OCCASIONAL BLADDER INFECTION-1979; TRICHOMONAS VAGINITIS-1985; GONORRHEA-1984; LAPROSCOPY-1987
	191014	MUSCULOSKELETAL	L BREAST-CYST REMOVAL-1962
		SPECIAL SENSES	CORRECTIVE LENSES-1969-ONGOING
Walsh	171015	CARDIOVASCULAR	LEG EDEMA, OCCASIONALLY 1997-ONGOING, HYPERTENSION SINCE 1994-ONGOING
		RENAL/URINARY TRACT	VAGINAL HERPES-1978-RESOLVED
		REPRODUCTIVE	HYSTERECTOMY WITH UNILATERAL OOPHERECTOMY-1989-RESOLVED
	171028	GASTROINTESTINAL	PANCREATITIS-1970-RESOLVED; HEMORROIDS-1981-RESOLVED
		GENITOURINARY	VENERAL DISEASE, 1970, TYPE UNKNOWN-CONT
		HEENT/MOUTH	NEARSIGHTED-1975-CONT
		NEUROLOGIC	TENSION HEADACHES, 1972-CONT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Walsh	171028	RENAL/URINARY TRACT	KIDNEY INFECTION-1970-STOPPED
	171061	ALLERGIC	SEASONAL ALLERGIES-1978; PERCODAN-CONT
		CARDIOVASCULAR	IRREGULAR HEART BEAT AGE 15-RESOLVED; HIGH BLOOD PRESSURE-AGE 15-RESOLVED
		GASTROINTESTINAL	HEMORRHOIDS, ONSET UNKNOWN-RESOLVED
		GYNECOLOGICAL	TOTAL ABDOMINAL HYSTERECTOMY -1/90; BILATERAL TUBAL LIGATION,1988-RESOLVED
		HEENT/MOUTH	TONSILLECTOMY-1964, TONSILITIS-RESOLVED, SINUS SURGERY-1991, TONSILLECTOMY-1964
		HEMATOLOGIC	LYME DISEASE 6/99 & CONTINUING
		METABOLIC/ENDOCRINE	ANEMIA, SECONDARY TO LYME DISEASE 5/99-CONT
		MUSCULOSKELETAL	BACK & JOINT PAIN ONSET UNKNOWN & CONTINUING
		NEUROLOGIC	TENSION HEADACHES, 1964-CONT
		PULMONARY	ASTHMA 1978-1982 (RESOLVED) SECONDARY TO SEASONAL ALLERGIES-RESOLVED
		RENAL/URINARY TRACT	KIDNEY INFECTION-1992-RESOLVED
	171062	ALLERGIC	CODEINE, FEELS SPACY, UNREAL 1960-CONT. ALSO ALLERGIC TO MOLD, POLLEN 1996,CONT. HYDROCODONE, 1996-CONT DIARRHEA

LIST3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Walsh	171062	REPRODUCTIVE	IRREGULAR MENSES, 1998-CONT
	171063	CARDIOVASCULAR	CHEST PAIN X1-1997,RESOLVED
		GASTROINTESTINAL	ULCERS 1989-CONT, INDIGESTION & HEART BURN 1989-CONT.
		HEENT/MOUTH	ORAL HERPES INFECTION 1999-CONT TUNNEL VISION 1991-CONT
		MUSCULOSKELETAL	MUSCULAR ACHES-NECK, 1997-CONT
		PULMONARY	SOB X1-1997, RESOLVED
	171064	ALLERGIC	INSECT BITES, CONT-CAUSES HIVES; SEASONAL ALLERGIES-1997-CONT
		DERMATOLOGIC	STRETCH MARKS - START DATE UNKNOWN - CONT, TATOO - START DATE UNKNOWN - CONT
Zajecka	201067	DERMATOLOGIC	FUNGAL INFECTION (R) TOE
		GASTROINTESTINAL	STATUS POST INGUINAL HERNIA REPAIR AS NEONAD
		HEENT/MOUTH	T & A AGE 4
		MUSCULOSKELETAL	S/P ANTHROSCOPIC SURGERY (R) KNEE AGE 12
	201068	CARDIOVASCULAR	HTN WHICH HAS BEEN WELL CONTROLLED

LIST3

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Medical History Descriptions - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Body System	Description
Zajecka	201091	GASTROINTESTINAL	GASTRITIS - WELL CONTROLLED
		PULMONARY	ASTHMA - WELL CONTROLLED
	201092	ALLERGIC	FOOD NKDA
		DERMATOLOGIC	BUNIONECTOMY 3-93
		RENAL/URINARY TRACT	S/P HYSTERECTOMY 11-99
	201123	ALLERGIC	SEASONAL ALLERGIES
		BLOCKED FALLOPIAN TUBES	EXPLORATORY LAP - TUBES SCARRED
		HEENT/MOUTH	HISTORY OF SINUSITIS, START 1998

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Amsterdam	11134	EXTREMITIES	Abnormal	MUSCLE ATROPHY (L) LOWER EXTREMITY		
		NERVOUS SYSTEM	Abnormal	DECREASED STRENGTH (L) LOWER EXTREMITY		
	11167	ABDOMEN	Abnormal	EXOGENOUS OBESITY		
		HEAD AND NECK	Normal	FUNDI NOT EXAMINED		
Barbee	21053	BREASTS		N/A		
Clayton	31019	ABDOMEN	Abnormal	LEFT UPPER QUADRANT TENDERNESS ; NO PALPABLE MASS		
		CHEST/LUNGS	Abnormal	TENDER COSTOCHONDRAL JOINTS		
		EXTREMITIES	Abnormal	CIGARETTE STAINS ON FINGERS		
	31020	EENT/MOUTH	Abnormal	UPPER DENTURES PRESENT		
		EXTREMITIES	Abnormal	LEFT HAND WITH MILD DEFORMITY AND DECREASED GRASP		
		HEAD AND NECK	Abnormal	3 SEBACEOUS CYSTS ON POSTERIOR SCALP		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Clayton	31020	NERVOUS SYSTEM	Abnormal	DECREASED GRASP OF LEFT HAND		
		SKIN	Abnormal	3 SEBACEOUS CYSTS ON POSTERIOR SCALP		
	31047	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	ANISOCORIA-LEFT GREATER THAN RIGHT		
	31048	BREASTS		NOT DONE		
		MENTATION	Abnormal	DEPRESSED		
		SKIN	Abnormal	FACIAL ACNE, MODERATE		
	31111	BREASTS		NOT DONE		
	31112	ABDOMEN	Abnormal	MILD (L) UPPER QUADRANT TENDERNESS WITHOUT MASS		
		BREASTS		NOT DONE		
Croft	231079	CHEST/LUNGS	Abnormal	FINE CRACKLES		
		EENT/MOUTH	Abnormal	ORAL ERYTHEMA		

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Croft	231079	EXTREMITIES	Abnormal	TOES AMPUTATED ON BOTH FEET		
		HEAD AND NECK	Abnormal	THYOROID ENLARGEMENT		
		HEART	Abnormal	HYPERTENSION		
	231080	BREASTS		NOT DONE		
		SKIN	Abnormal	S/P MOH LASER SURGERY LEFT LEG		
	231119	SKIN	Abnormal	DRY		
	231120	SKIN	Abnormal	SURGICAL SCARRING		
	231139	SKIN	Abnormal	ACNE		
Delgado	41069	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	OROPHARYNX MILDY RED, NERVES WITH MUCOUS DISCHARGE		
	41070	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	ADIE'S PUPIL - NOW REACTIVE DILATED LEFT PUPIL		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Delgado	41070	EXTREMITIES	Abnormal	LOWER EXTREMITIES COOL TO TOUCH VARICOSE VEINS - BILATERALLY		
		OTHER ABNL. PE FINDINGS?	Abnormal	OBESITY DECREASE ROM OF (L) HIP AGAINST RESISTANCE		
		SKIN	Abnormal	WARM, DRY PATCHES ON ARMS AND ELBOWS WITH SCALING SCAR,RUQ (GALLBLADDER)		
	41093	ABDOMEN	Abnormal	MILD TENDERNESS TO DEEP PALPATION LEFT LOWER QUADRANT		
		BREASTS		NOT DONE		
		CHEST/LUNGS	Abnormal	SOB "ONGOING"		
		SKIN	Abnormal	MILD ROSACEA BRIDGE OF NOSE "ONGOING"; MILD ACNE BACK AREA		
	41094	BREASTS		DEFERRED PER PT REQUEST - SEES GYN 1/20/99	JENNIFER SNYDOR MD IS PLP. LAST PE 1 YR AGO; ANTHEA DIXON MD IS OB/GYN	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Delgado	41094	HEAD AND NECK	Abnormal	BILAT ANTERIOR CERVICAL ADENOPATHY 2X4MM, NONTENDER, MOVABLE	JENNIFER SNYDOR MD IS PLP. LAST PE 1 YR AGO; ANTHEA DIXON MD IS OB/GYN	
		LYMPH NODES	Abnormal	SEE ABOVE NECK	JENNIFER SNYDOR MD IS PLP. LAST PE 1 YR AGO; ANTHEA DIXON MD IS OB/GYN	
DuBoff	311017	ABDOMEN	Abnormal	OBESE		
		BACK/SPINE	Abnormal	SURGICAL SCAR LEFT SCAPULA; SURGICAL SCAR LUMBAR AREA		
		EXTREMITIES	Abnormal	METATARSALS 1,2 AND 3 ABSENT		
		SKIN	Abnormal	RESOLVING HERPES LESION RIGHT CHEST AND BACK; ERYTHEMA SURROUNDING MOUTH		
	311018	SKIN	Abnormal	RIGHT LOWER QUADRANT ABDOMINAL SURGICAL SCAR		
	311115	BACK/SPINE	Abnormal	TATTOO LUMBAR SPINE		
		EXTREMITIES	Abnormal	SURGICAL SCAR LEFT FOOT		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
DuBoff	311116	ABDOMEN	Abnormal	RIGHT LOWER QUADRANT SURGICAL SCAR; MIDLINE SURGICAL SCAR; SUPRAPUBIC SURGICAL SCAR;		
		BREASTS	Abnormal	BILTERAL IMPLANTS		
		HEAD AND NECK	Abnormal	SURGICAL SCAR ANTERIOR NECK		
Dunner	211040	ABDOMEN	Abnormal	PROTRUBERANT (NCS)		
		NERVOUS SYSTEM	Abnormal	MILD HORIZONTAL NYSTAGMUS; MILD FINGER FLATTENINGS W/ ROMBERG TESTING NCS		
	211110	BACK/SPINE	Abnormal	THORACIC SPINE CURVATURE(MOD) TO RT WITH RT SHOULDER SLOPING		
	211145	ABDOMEN	Abnormal	PROTRUBERANT		
		OTHER ABNL. PE FINDINGS?	Abnormal	GENERAL APPEARANCE OBESE		
	211146	ABDOMEN	Abnormal	PROTUBERANT		
		BACK/SPINE	Abnormal	MILD CERVICAL SPINE CURVATURE		

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Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Dunner	211146	HEART	Abnormal	SL MURMUR II/VI-BEST HEARD SITTING ONLY-AORTIC & PULMONIC		
	211147	HEART	Abnormal	SPLIT S1,S2 CLOSING SNAP NCS		
Fava	51113	BREASTS		NOT DONE		
	51142	BREASTS		NOT DONE		
		ENDOCRINE		NOT DONE		
		LYMPH NODES		NOT DONE		
Ferguson	241032	BREASTS		NOT DONE	BREAST EXAM NOT DONE	
	241073	BREASTS		NOT DONE		
Gilmer	61081	BREASTS		NOT DONE		
		EXTREMITIES	Abnormal	RIGHT KNEE SWELLING		
		OTHER ABNL. PE FINDINGS?	Abnormal	REDDISH FINGERS		
	61082	BREASTS		NOT DONE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Helfing	81003	BACK/SPINE	Abnormal	DECREASED ROM (MILD)		
		EXTREMITIES	Abnormal	ARTHRITIS IN HANDS, SHOULDER AND BACK		
	81004	BREASTS		NOT DONE		
	81051	BREASTS		NOT DONE		
	81052	BREASTS		NOT DONE		
	81075	BREASTS		NOT DONE		
		OTHER ABNL. PE FINDINGS?	Abnormal	OBESITY		
	81103	BREASTS		NOT DONE		
Hoopes	271021	BREASTS		NOT DONE	PE WAS PERFORMED 7/7/99	
		NERVOUS SYSTEM	Abnormal	HYPERACTIVE REFLEXES LE 2+ , UE1+	PE WAS PERFORMED 7/7/99	
	271022	BREASTS		NOT DONE		
		NERVOUS SYSTEM	Abnormal	2+ LE; 1+ UE SYMETRICAL		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Hoopes	271045	BREASTS		NOT DONE - PT DEFERRED.		
		NERVOUS SYSTEM	Abnormal	2+LE SYMETRICAL; 1+UE SYMETRICAL		
Liebowitz	91005	BREASTS		NOT DONE		
	91006	BREASTS		NOT DONE		
	91035	BREASTS		NOT DONE		
	91036	BREASTS		N/A; NOT DONE		
	91097	BREASTS		NOT DONE		
	91137	BREASTS		NOT DONE		
		OTHER ABNL. PE FINDINGS?	Abnormal	MODERATE OBESITY		
	91138	BREASTS		NOT DONE		
Londborg	101010	BREASTS	Abnormal	MULTIPLE MOVEABLE NON-TENDER CYSTS IN BOTH BREASTS	CURRENT T4/TSH LEVELS ARE WNL	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Londborg	101010	EXTREMITIES	Abnormal	HEALED SURGICAL SCAR LEFT LOWER LEG TO IGUINAL AREA-VEIN HARVEST SITE FOR CABG	CURRENT T4/TSH LEVELS ARE WNL	
		HEAD AND NECK	Abnormal	THYROID GLAND ENLARGED, UNIFORM, SMOOTH AND MOVABLE.	CURRENT T4/TSH LEVELS ARE WNL	
		OTHER ABNL. PE FINDINGS?	Abnormal	ACHES AND PAINS (NONSPECIFIC) ONGOING	CURRENT T4/TSH LEVELS ARE WNL	
		SKIN	Abnormal	HEALED SURGICAL SCAR, ANTERIOR CHEST FROM PREVIOUS CABG SURGERY	CURRENT T4/TSH LEVELS ARE WNL	
	101043	SKIN	Abnormal	CYSTIC ACNE ON FACE, NECK & BACK		
	101044	SKIN	Abnormal	ACNE PUSTULES ON CHIN		
Lydiard	221034	BREASTS	Abnormal	OPERATION SCARS FOR BREAST IMPLANT 1988		
	221129	BREASTS		NA		
	221130	BREASTS	Abnormal	OPERATION SCAR, BREAST AUGMENTATION		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
McGrath	111058	OTHER ABNL. PE FINDINGS?	Abnormal	OBESITY	NO CONTRAINDICATION TO STUDY PARTICIPATION	
	111171	ENDOCRINE	Abnormal	OBESITY	PHYSICAL DELAYED DUE TO NEED TO TREAT HYPERTENSION	
		HEART	Abnormal	HEART MURMOR, PULMONIC AREA	PHYSICAL DELAYED DUE TO NEED TO TREAT HYPERTENSION	
		SKIN	Abnormal	CONGENITAL LESION ON FACE	PHYSICAL DELAYED DUE TO NEED TO TREAT HYPERTENSION	
Munjack	131011	BREASTS		NOT DONE		
	131012	BREASTS		NOT DONE		
	131071	EENT/MOUTH	Abnormal	DECREASED HEARING (L) EAR, NCS		
		SKIN	Abnormal	TATOO (L) ANTERIOR CHEST		
	131072	BREASTS		NOT DONE		
	131125	BREASTS		NOT DONE-DEFERRED FOR PT'S COMFORT		
	131126	BREASTS		NOT DONE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Munjack	131143	BREASTS		NOT DONE		
	131144	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	(L) EYE DOES NOT ADDUCT FAST MIDLINE, NCS		
Nelson	141041	BREASTS		NOT DONE		
		MENTATION	Abnormal	SOME MILD MEMORY DIFFICULTIES		
Oldroyd	321055	SKIN	Abnormal	SCAR, HEALED FOREHEAD, CHIN		
	321056	SKIN	Abnormal	HEALED SCAR LEFT FOREARM		
	321087	EENT/MOUTH	Abnormal	HEARING AIDE, LEFT		
		SKIN	Abnormal	SCAR, NECK, HEALED DUE TO SURGERY TO REMOVE CYST		
Prover	261023	ABDOMEN	Abnormal	OBESE		
		BREASTS		NOT DONE		
		LYMPH NODES	Abnormal	SMALL PEA SIZE (R) NECK		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Rapaport	151037	ABDOMEN	Abnormal	OBESE; OBLIQUE SCAR RUQ	NORMAL PE	
	151038	ABDOMEN	Abnormal	CICATRIX-LOWER QUADRANT SECONDARY S/P BLADDER SURGERY: HX CARCINOMA	ESSENTIALLY STABLE MEDICALLY, EXCEPT HX BLADDER CARCINOMA-SURGERY IN AUG'99. CURRENTLY FOLLOW UP AT 3 MTHS AT BALBRA HOSP (NAVY) WITH UROLOGIST.	CLARIFY WITH SPONSOR & MEDICAL MONITOR PRIOR TO ENROLLMENT.
		MENTATION	Abnormal	DEPRESSED	ESSENTIALLY STABLE MEDICALLY, EXCEPT HX BLADDER CARCINOMA-SURGERY IN AUG'99. CURRENTLY FOLLOW UP AT 3 MTHS AT BALBRA HOSP (NAVY) WITH UROLOGIST.	CLARIFY WITH SPONSOR & MEDICAL MONITOR PRIOR TO ENROLLMENT.
	151085	BACK/SPINE	Abnormal	BEGAN IN 1990 MILD MUSCULOSKE-LETAL PAIN L1-L5		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT
		HEART	Abnormal	1955 0 SEQUELA, 2/6 SEM (HX BENIGN) 0 RX, 0 CU HISTORY		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT

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Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Rapaport	151085	MENTATION	Abnormal	DEPRESSED		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT
	151086	EXTREMITIES	Abnormal	RASH ON R OLECRANON AREA	RASH ON (R) ELBOW-OTHERWISE NORMAL	
	151095	ABDOMEN	Abnormal	CICATRIX RLQ SECONDARY TO APPENDECTOMY, SECONDARY TO HERNIA THERAPY	-ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
		MENTATION	Abnormal	DEPRESSION	-ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
		OTHER ABNL. PE FINDINGS?	Abnormal	RANGE OF MOTION ADEQUATE WITHIN NORMAL LEVELS; L KNEE MILD TENDERNESS WITH PALPATIONS (TAKES IBUPROFEN PRN)	-ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
	151096	ABDOMEN	Abnormal	S/P APPENDECTOMY 1987, CICATRIX RLQ		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT

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Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Rapaport	151096	BACK/SPINE	Abnormal	MILD MUSCULOSKELETAL PAIN L1-L5		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT
		MENTATION	Abnormal	DEPRESSED		ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT
	151099	BREASTS	Normal	(BILATERAL IMPLANTS)	NORMAL PHYSICAL EXAM	
		MENTATION	Abnormal	DEPRESSION	NORMAL PHYSICAL EXAM	
		OTHER ABNL. PE FINDINGS?	Normal	GU NOT TESTED	NORMAL PHYSICAL EXAM	
	151100	EXTREMITIES	Abnormal	SORE RIGHT ANKLE (TORSION) - 9/99		
	151117	MENTATION	Abnormal	DEPRESSED	ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
	151118	BACK/SPINE	Abnormal	MILD TENDERNESS (R) SHOULDER	ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Rapaport	151118	MENTATION	Abnormal	DEPRESSED	ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
	151153	EENT/MOUTH	Abnormal	(L) EYE - S/P SURGERY PTOSIS CICATRIX PRESENT WITH MILD EDEMA & ECCHEYMOSIS PRESENT	RECENT (L) EYE PTOSIS S/P SURGERY, NEED TO OK WITH MEDICAL MONITOR/SPONSOR; OTHERWISE ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
		MENTATION	Abnormal	DEPRESSED	RECENT (L) EYE PTOSIS S/P SURGERY, NEED TO OK WITH MEDICAL MONITOR/SPONSOR; OTHERWISE ESSENTIALLY NO SEVERE MEDICAL PROBLEMS TO PREVENT ENROLLMENT	
Smith	281025	BREASTS		NOT DONE		
		ENDOCRINE		NOT DONE		
	281026	BREASTS		NOT DONE		
	281101	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	POOR DENTATION		

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Smith	281101	SKIN	Abnormal	MULTIPLE WELL HEALED SCARS		
	281102	BREASTS		NOT DONE		
	281107	BREASTS		NOT DONE		
	281108	BREASTS		NOT DONE		
		MENTATION		NOT DONE		
Telew	171027	BREASTS	0	NOT DONE		
Thase	181083	NERVOUS SYSTEM	Abnormal	DTRS SLIGHTLY HYPER-REFLEXIVE SECODARY TO SSRI		
	181084	ABDOMEN	Abnormal	LOWER ABDOMEN-MULTIPLE LIPOMAS		
		BACK/SPINE	Abnormal	MULTIPLE LIPOMAS		
		EXTREMITIES	Abnormal	FOREARMS - MULTIPLE LIPOMAS		
	181105	BREASTS		EXAM NOT DONE		

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Thase	181105	SKIN	Abnormal	SLIGHT REDNESS OF FACE, PARTICULARLY THE MOLAR ARCHES; REDNESS BOTH PALMS SECONDARY TO CHAPPING WELL HEALED SURGICAL SCAR ON RIGHT POSTERIOR SHOULDER		
	181136	BREASTS		NOT DONE		
		EENT/MOUTH	Abnormal	DIMINISHED ABILITY TO DISCERN WHISPER, NO OTHER ABNORMALITY		
Trivedi	191013	BACK/SPINE	Abnormal	+ SPINAL LORDOSIS (SLIGHT)		
		BREASTS		NOT DONE		
		HEART	Abnormal	+ HEART MURMUR- +III/IV SYTOLIC M		
	191014	BREASTS	Abnormal	HEALED SURGICAL SCAR OVER (L) BREAST		
		HEAD AND NECK	Abnormal	(+) NON-TENDER (R) ANTERIOR CERVICAL LYMPHADENOPATHY		
		LYMPH NODES	Abnormal	(AS ABOVE-NECK)		

LIST4

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Physical Examination Abnormalities - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	PE Item	Normal/ Abnormal	Descriptions	Comment	Additional Comment
Trivedi	191014	SKIN	Abnormal	(AS ABOVE-BREASTS)		
Walsh	171015	BREASTS		NOT DONE		
	171028	BREASTS		NOT DONE		
	171061	BREASTS		NOT DONE		
		EXTREMITIES	Abnormal	TRACE PRE-TIBIAL EDEMA, BILATERAL		
	171062	BREASTS		NOT DONE		
Zajecka	201067	EXTREMITIES	Abnormal	FUNGAL INFECTION R BIG TOE	MEDICALLY STABLE	
		MENTATION	Abnormal	MILD PSYCHO RETARDATION	MEDICALLY STABLE	
	201092	BREASTS		NOT DONE	MEDICALLY STABLE	
	201123	BREASTS		NOT DONE	MEDICALLY STABLE	

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Amsterdam	11065	Screen	1	296.33	NONE, NEITHER MELANCHOLIC NOR ATYPICAL	51	No	No
	11066	Screen	1	296.33	NONE, NEITHER MELANCHOLIC OR MIXED OR ATYPICAL	45	No	No
		Week 8	1	296.33	NONE	70	No	No
		Week 32/Final	1	296.33	NONE	50	No	No
	11133	Screen	1	296.33	NONE, NEITHER MELANCHOLIC,ATYPICAL, OR MIXED	54	No	No
		Week 8	1	296.33	NONE	60	No	No
	11134	Screen	1	296.33	NONE (NEITHER ATYPICAL,MELANCHOLIC,CATONIC OR MIXED)	60	Yes	Yes
		Week 8	1	296.33	NONE; RECURRENT MAJOR DEPRESSION; NEITHER ATYPICAL, MELANCHOLIC, MIXED NOR CATATONIC	83	Yes	No
	11159	Screen	1	296.32	MAJOR DEPRESSION, MELANCHOLIC, RECURRENT	55	No	No
		Week 8	1	296.32	MELANCHOLIC	55	No	No
	11160	Screen	1	296.32	NONE	60	No	No
		Week 8	1	296.32	NONE	68	No	No
	11167	Screen	1	296.32	NONE	50	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Amsterdam	11167	Week 8	1	296.32	NONE	86	No	No
Barbee	21053	Screen	1	296.31	ATYPICAL	65	No	No
			3	458.0	HYPOTENSION	65	No	No
				574.5	CHOLEDOCHOLITIASIS	65	No	No
		Week 8	1	296.31	ATYPICAL FEATURES	50	No	No
			3	458.0	HYPOTENSION	50	No	No
				574.50	CHOLEDOCHOLITIASIS	50	No	No
Clayton	31019	Screen	1	296.33	MELANCHOLIC	50	No	Yes
			3	733.6	COSTOCHONDRITIS	50	No	Yes
		Week 8	1	296.35	MELANCHOLIC	57	No	Yes
			3	733.6	COSTOCHONDRITIS	57	No	Yes
		Week 32/Final	1	296.32	MELANCHOLIC	52	No	Yes
			3	733.6	COSTOCHONORITIS	52	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Clayton	31020	Screen	1	296.22	MIXED	52	No	No
			3	531.	HISTORY OF GASTRIC ULCERS	52	No	No
				959.4	S/P HAND INJURY NOS	52	No	No
		Week 8	1	296.26	MIXED	70	No	No
			3	531.	HISTORY OF GASTRIC ULCERS	70	No	No
				959.4	S/P HAND INJURY NOS	70	No	No
		Week 32/Final	1	296.26	MIXED	70	No	No
			3	531.	HISTORY OF GASTRIC ULCERS	70	No	No
				959.4	S/P HAND INJURY NOS	70	No	No
	31047	Screen	1	296.32	ATYPICAL	60	No	Yes
			3	564.1	IRRITABLE BOWEL SYNDROME	60	No	Yes
				722.10	HERNIATED L4/L5 DISC	60	No	Yes
		Week 8	1	296.32	ATYPICAL	60	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Clayton	31047	Week 8	3	564.1	IRRITABLE BOWEL SYNOROME	60	No	Yes
				722.10	HERNIATED L4/L5 DISC	60	No	Yes
	31048	Screen	1	296.32	MELANCHOLIC	60	No	Yes
				300.40	DYSTHYMIA, PRIMARY TIME, EARLY ONSET	60	No	Yes
			3	564.1	IRRITABLE BOWEL SYNDROME	60	No	Yes
		Week 8	1	296.35	MELANCHOLIC	68	No	Yes
				300.40	DYSTHYMIA, PRIMARY TYPE, EARLY ONSET	68	No	Yes
			3	564.1	IRRITABLE BOWEL SYNDROME	68	No	Yes
		Week 32/Final	1	296.35	MELANCHOLIC	68	No	Yes
				300.40	DYSTHYMIA,PRIMARY TYPE, EARLY ONSET	68	No	Yes
			3	564.1	IRRITABLE BOWEL SYNDROME	68	No	Yes
	31111	Screen	1	296.33	ATYPICAL	62	No	No
		Week 8	1	296.33	ATYPICAL	62	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Clayton	31112	Screen	1	296.33	MELANCHOLIC	62	No	No
			3	244.00	HYPOTHYROIDISM	62	No	No
		Week 8	1	296.31	MELANCHOLIC	72	No	No
			3	244.00	HYPOTHYROIDISM	72	No	No
Croft	231001	Screen	1	296.32	MIXED	50	No	No
			3	564.0	CONSTIPATION-CHRONIC	50	No	No
		Week 8	1	296.31	MIXED	68	No	No
		Week 32/Final	1	296.32	MIXED	70	No	No
			3	564.0	CHRONIC CONSTIPATION	70	No	No
	231002	Screen	1	296.32	MIXED	60	No	No
		Week 8	1	296.33	MIXED	55	No	No
			3	724.3	SCIATIC NERVE IRRITATION	55	No	No
	231079	Screen	1	296.32	MIXED	58	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Croft	231079	Week 8	1	296.32	MDD-RECURRENT MIXED	68	No	No
		Week 32/Final	1	296.32	MIXED	75	No	No
	231080	Screen	1	296.32	MELANCHOLIC	58	No	No
		Week 8	1	296.32	MELANCHOLIC	58	No	No
	231119	Screen	1	296.32	MELANCHOLIC	50	No	No
		Week 8	1	296.32	MELANCHOLIC	70	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	59	No	No
	231120	Screen	1	296.3	MELANCHOLIC	58	No	No
		Week 8	1	296.32	MELANCHOLIC	75	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	60	No	No
	231139	Screen	1	296.32	MELANCHOLIC	50	No	No
		Week 8	1	296.32	MELANCHOLIC	80	No	No
Delgado	41069	Screen	1	296.20	MELANCHOLIC	55	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Delgado	41069	Screen	1	300.23	SOCIAL PHOBIA	55	No	No
				300.29	SPECIFIC PHOBIA	55	No	No
				300.40	DYSTHYMIA EALRY ONSET	55	No	No
			3	477.09	SEASONAL ALLERGIES	55	No	No
		Week 8	1	296.20	MELANCHOLIC	90	No	No
				300.23	SOCIAL PHOBIA	90	No	No
				300.29	SPECIFIC PHOBIA	90	No	No
				300.40	DYSTHYMIA EARLY ONSET	90	No	No
			3	477.09	SEASONAL ALLERGIES	90	No	No
	41070	Screen	1	296.3X	MAJOR DEPRESSION WITH ATYPICAL FEATURES	57	No	No
		Week 8	1	296.30	ATYPICAL	60	No	No
	41093	Screen	1	296.22	MAJOR DEPRESSION-MELANCHOLIC	60	No	No
		Week 8	1	296.22	MDE IN REMISSION	75	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Delgado	41093	Week 32/Final	1	296.22	"MELANCHOLIC" RELAPSE	61	No	No
	41094	Screen	1	296.20	MAJOR DEPRESSION "MELANCHOLIC"	60	No	No
		Week 8	1	296.20	MDE "MELANCHOLIC" IN REMISSION	85	No	No
		Week 32/Final	1	296.20	"MELANCHOLIC" RELAPSE	60	No	No
DuBoff	311017	Screen	1	296.32	NONE	58	No	
			2	V71.09	NONE	58	No	
			3	000.00	NONE	58	No	
		Week 8	1	296.35	MAJOR DEPRESSIVE DISORDER, RECURRENT, IN PARTIAL REMISSION	69	No	No
		Week 32/Final	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE	58	No	No
	311018	Screen	1	296.32	MELANCHOLIC FEATURES	50	No	No
			2	V71.09	NONE	50	No	No
			3	000.00	NONE	50	No	No
		Week 8	1	296.32	MELANCHOLIC FEATURES	68	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
DuBoff	311018	Week 8	2	V71.09	NONE	68	No	No
			3	000.00	NONE	68	No	No
	311115	Screen	1	296.32	ATYPICAL FEATURES	60	No	No
			2	V71.09	NONE	60	No	No
			3	000.00	NONE	60	No	No
		Week 8	1	296.32	MAJOR DEPRESSIVE DISORDER IN FULL REMISSION	80	No	No
		Week 32/Final	1	296.25	ATYPICAL	70	No	No
			2	V71.09	NO DIAGNOSIS MADE	70	No	No
			3	000.00	NONE MADE	70	No	No
	311116	Screen	1	296.32	NONE	56	No	No
Dunner	211039	Screen	1	296.22	MELANCHOLIC	60	Yes	Yes
		Week 8	1	296.22	CHRONIC MDD	60	No	No
	211040	Screen	1	296.22	ATYPICAL	55	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Dunner	211040	Screen	3	346.10	MIGRAINE HEADACHE	55	No	No
		Week 8	1	296.26	ATYPICAL	80	No	No
			3	346.10	MIGRAINE HEADACHE	80	No	No
		Week 32/Final	1	296.22	ATYPICAL	65	No	No
	211109	Screen	1	296.22	MIXED	55	No	Yes
		Week 8	1	296.21	MIXED	70	No	No
		Week 32/Final	1	296.22	MIXED	60	No	Yes
	211110	Screen	1	296.32	MELANCHOLIC	55	No	Yes
			3	401.9	ESSENTIAL HYPERTENSION	55	No	Yes
		Week 8	1	296.32	MELANCHOLIC	85	No	No
			3	401.9	ESSENTIAL HYPERTENSION	85	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	65	No	No
	211145	Screen	1	296.22	MELANCHOLIC	55	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Dunner	211145	Week 8	1	296.23	MELANCHOLIC	55	No	No
	211146	Screen	1	296.32	MIXED	55	No	No
		Week 8	1	296.31	MIXED	80	No	No
	211147	Screen	1	296.23	MELANCHOLIC	50	Yes	Yes
				305.00	ALCOHOL ABUSE IN REMISSION	50	Yes	Yes
		Week 8	1	296.23	MELANCHOLIC	45	Yes	Yes
				305.00	ALCOHOL ABUSE IN REMISSION	45	Yes	Yes
Fava	51113	Screen	1	296.33	MAJOR DEPRESSION, MELANCHOLIC	45	No	Yes
				307.50	BEING EATING DISORDER	45	No	Yes
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER MELANCHOLIC	50	No	Yes
				307.50	BINGE EATING DISORDER	50	No	Yes
			2	799.90	DEFERRED	50	No	Yes
			3	278.00	OBESITY	50	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Fava	51113	Week 8	3	401.90	HYPERTENSION	50	No	Yes
	51114	Screen	1	296.33	MAJOR DEPRESSION DISORDER RECURRECT, SEVERE MELANCHOLIC TYPE	40	Yes	No
			2	799.9	DEFERRED	40	Yes	No
			3	000.00	NONE	40	Yes	No
	51141	Screen	1	296.33	NONE	50	No	Yes
				300.21	PANIC WITH AGARPHOBIA	50	No	Yes
				307.50	BINGE FATING DISORDER	50	No	Yes
				309.81	PTSD, CHRONIC	50	No	Yes
			2	799.9	DEFERRED	50	No	Yes
		Week 8	1	296.33	MDD, NONE	40	No	Yes
				300.21	PANIC WITH AGROPHOBIA	40	No	Yes
				307.50	BINGE EATING DISORDER	40	No	Yes
				309.81	PTSD, CHRONIC	40	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Fava	51141	Week 8	2	799.9	DEFERRED	40	No	Yes
	51142	Screen	1	296.30	MDD, NONE	50	No	Yes
			2	000.00	NONE	50	No	Yes
			3	599.00	RECURRENT URINARY TRACT INFECTIONS	50	No	Yes
		Week 8	1	296.35	MDD, NONE	90	No	No
			3	599.00	RECURRENT URINARY TRACT INFECTIONS	90	No	No
Ferguson	241031	Screen	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT MODERATE WITH MELANCHOLIC FEATURES	60	No	No
			2	V71.09	NO DIAGNOSIS	60	No	No
			3	401.90	HYPERTENSION	60	No	No
				427.32	ATRIAL FLUTTER	60	No	No
		Week 8	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT MELANCHOLIC	60	No	No
			2	V71.09	NO DIAGNOSIS	60	No	No
			3	401.90	HYPERTENSION	60	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Ferguson	241031	Week 8	3	427.32	ATRIAL FLUTTER	60	No	No
	241032	Screen	1	296.32	NONE	68	No	No
			2	V71.09	NONE	68	No	No
			3	V71.09	NONE	68	No	No
	241073	Screen	1	296.32	NONE	55	No	No
		Week 8	1	296.32	NONE	53	No	No
	241074	Screen	1	296.32	NONE	58	Yes	No
			2	V71.09	NONE	58	Yes	No
			3	000.00	NONE	58	Yes	No
		Week 8	1	296.32	NONE	55	No	No
			2	V71.09	NONE	55	No	No
			3	000.00	NONE	55	No	No
Gilmer	61081	Screen	1	296.23	MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE SEVERE, MELANCHOLIC	50	No	Yes

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Gilmer	61081	Screen	1	300.40	DYSTHYMIA, EARLY ONSET	50	No	Yes
				304.40	AMPHETAMINE DEPENDENCE, SUSTAINED FULL REMISSION	50	No	Yes
			2	799.9	DIAGNOSIS DEFERRED	50	No	Yes
			3	443.00	RAYNAUD'S DISEASE	50	No	Yes
				995.00	PENICILLIN ALLERGY	50	No	Yes
		Week 8	1	296.23	MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE, SEVERE, MELANCHOLIC	50	No	Yes
				300.40	DYSTHYMIA, EARLY ONSET	50	No	Yes
				304.40	AMPHETAMINE DEPENDENCE, SUSTAINED FULL REMISSION	50	No	Yes
			2	299.9	DIAGNOSIS DEFERRED	50	No	Yes
			3	443.00	RAYNAUD'S DISEASE	50	No	Yes
				995.00	PENICILLIN ALLERGY	50	No	Yes
	61082	Screen	1	296.33	MELANCHOLIC	35	No	No
			3	477.90	SEASONAL RHINITIS	35	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Gilmer	61082	Screen	3	530.81	ACID REFLUX (ESOPHAGEAL)	35	No	No
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER, MELANCHOLIC,RECURRENT, SEVERE	35	No	No
			3	477.90	SEASONAL RHINITIS	35	No	No
				530.81	ESOPHAGEAL REFLUX	35	No	No
Halbreich	71077	Screen	1	296.32	MAJOR DEPRESSION; MELANCHOLIC FEATURE	65	No	No
Helfing	81003	Screen	1	296.3X	NO FEATURES PER MD	52	No	No
				307.89	PAIN DISORDER ASSOCIATED WITH PSYCHOLOGICAL FACTORS AND GENERAL MEDICAL CONDITION	52	No	No
			3	729.1X	FIBROMYALGIA	52	No	No
				733.XX	OSTEOPOROSIS	52	No	No
		Week 8	1	296.31	NO FEATURES PER MD	65	No	No
				307.89	PAIN DISORDER	65	No	No
			3	564.1X	IRRITABLE BOWEL SYNDROME	65	No	No
				715.9X	OSTEOARTHRITIS	65	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Helfing	81004	Screen	1	296.3	NONE NO FEATURES PER MD	60	No	No
		Week 8	1	296.31	NONE, NO FEATURES PER MD	61	No	No
	81051	Screen	1	296.3X	NONE, NO FEATURES PER MD	55	No	No
			2	799.9X	DEFERRED	55	No	No
			3	564.1	INFLAMMATORY BOWEL DISEASE	55	No	No
	81052	Screen	1	296.31	NONE, NO FEATURE PER MD	40	No	No
				303.93	ALCOHOL ABUSE IN REMISSION	40	No	No
			3	307.81	HISTORY OF TENSION HEADACHES	40	No	No
				724.2X	HX OF LOW BACK PAIN	40	No	No
		Week 8	1	296.31	NONE, NO FEATURES PER MD	30	No	No
				303.93	ALCOHOL ABUSE	30	No	No
			3	307.81	HISTORY OF TENSION HEADACHES	30	No	No
				724.2X	HISTORY OF LOW BACK PAIN	30	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Helfing	81075	Screen	1	296.3X	NO FEATURES PER MD	65	No	No
			3	346.9X	MIGRAINE HEADACHES	65	No	No
		Week 8	1	296.3X	NO FEATURES PER MD	60	No	No
		Week 32/Final	1	296.2X	NO FEATURES PER MD	70	No	No
	81076	Screen	1	296.3X	NO FEATURES PER MD	60	No	No
		Week 8	1	296.30	NO FEATURES PER MD	65	No	No
		Week 32/Final	1	296.3X	NO FEATURES PER MD	75	No	No
	81103	Screen	1	296.3	NO FEATURES PER MD	60	No	No
			3	723.1	CERVICAL NECK PAIN	60	No	No
		Week 8	1	296.20	NO FEATURES PER MD	64	No	No
		Week 32/Final	1	296.3	MAJOR DEPRESSION, RECURRENT	60	No	No
			2	799.99	NONE	60	No	No
Hoopes	271021	Screen	1	296.25	MIXED	45	Yes	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Hoopes	271021	Week 8	1	296.25	MAJOR DEPRESSIVE, SINGLE EPISODE, PARITAL REMISSION, MIXED	50	No	No
	271022	Screen	1	296.35	ATYPICAL; MAJOR DEPRESSION, RECURRENT, PART REMISSION	50	No	Yes
		Week 8	1	296.35	ATYPICAL	70	No	Yes
		Week 32/Final	1	296.35	ATYPICAL	50	No	No
	271045	Screen	1	296.30	MELANCHOLIC	45	No	Yes
		Week 8	1	296.32	MELANCHOLIC	45	No	Yes
Liebowitz	91005	Screen	1	296.32	ATYPICAL	55	No	Yes
			3	244.90	HYPOTHYROIDISM	55	No	Yes
		Week 8	1	296.32	ATYPICAL	45	No	Yes
			3	244.90	HYPOTHYROIDISM	45	No	Yes
	91006	Screen	1	296.32	ATYPICAL	60	Yes	Yes
		Week 8	1	296.32	MAJOR DEPRESSIVE DISORDER, ATYPICAL	58	No	Yes
	91035	Screen	1	296.3	ATYPICAL	50	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Liebowitz	91035	Week 8	1	296.33	ATYPICAL	50	No	No
	91036	Screen	1	296.33	DEPRESSIVE DISORDER, RECURRENT & SEVERE; MELANCHOLIC	60	Yes	Yes
	91097	Screen	1	296.3	MIXED	60	No	Yes
			3	242.9	HYPOTHYROIDISM	60	No	Yes
		Week 8	1	296.26	NONE	90	No	No
			2	000.00	NONE	90	No	No
			3	242.9	HYPOTHYROIDISM	90	No	No
	91098	Screen	1	296.32	MIXED	60	No	Yes
			2	000.00	NONE	60	No	Yes
			3	000.00	NONE	60	No	Yes
		Week 8	1	296.32	MDD-MODERATE	70	No	Yes
	91137	Screen	1	296.30	MIXED	60	No	No
			3	278.00	HX OBESITY	60	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Liebowitz	91137	Week 8	1	296.30	MIXED	60	No	Yes
			3	278.00	OBESITY	60	No	Yes
	91138	Screen	1	296.3	MIXED	55	No	Yes
		Week 8	1	296.32	ATYPICAL	55	No	Yes
Londborg	101009	Screen	1	296.22	CHRONIC WITH MELANCHOLIA	60	No	No
		Week 8	1	296.22	CHRONIC WITH MELANCHOLIA	60	No	No
	101010	Screen	1	296.33	NONE	45	No	Yes
				309.81	PTSD IN REMISSION	45	No	Yes
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER	58	No	Yes
				309.81	PTSD IN REMISSION	58	No	Yes
	101043	Screen	1	296.32	NONE	55	No	No
				305.60	COCAINE ABUSE (FULL REMISSION)	55	No	No
				309.81	PTSD (FULL REMISSION)	55	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Londborg	101043	Week 8	1	296.36	NONE	85	No	No
				305.60	COCAINE ABUSE IN FULL REMISSION	85	No	No
				309.81	PTSD IN FULL REMISSION	85	No	No
		Week 32/Final	1	296.32	NONE	68	No	No
				305.60	COCAINE ABUSE IN FULL REMISSION	68	No	No
				309.81	PTSD IN FULL REMISSION	68	No	No
	101044	Screen	1	296.22	NONE	60	No	No
			2	V71.09	NO DIAGNOSIS	60	No	No
			3	V71.09	NO DIAGNOSIS	60	No	No
		Week 8	1	296.22	NONE	80	No	No
		Week 32/Final	1	296.25	NONE	82	No	No
Lydiard	221033	Screen	1	296.32	NONE	55	No	No
			3	306.8	BRUXISM	55	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Lydiard	221033	Week 8	1	296.36	NONE	65	No	No
			3	306.8	BRUXISM	65	No	No
		Week 32/Final	1	296.06	MAJOR DEPRESSIVE DISORDER RECURRENT IN FULL REMISSION	75	No	No
	221034	Screen	1	296.30	NONE	60	No	No
		Week 8	1	296.30	NONE	50	No	No
	221129	Screen	1	296.30	NONE	55	No	No
		Week 8	1	296.30	NONE	54	No	No
	221130	Screen	1	296.30	NONE	55	No	No
McGrath	111057	Screen	1	296.22	MELANCHOLIC, MAJOR DEPRESSION, SINGLE EP, MDD X6YRS	60	No	Yes
				300.40	DYSTHYMIA X 7 YRS	60	No	Yes
			2	799.90	DEFERRED	60	No	Yes
		Week 8	1	296.22	MAJOR DEPRESSION, MELANCHOLIC, SINGLE EPISODE 6 YEARS	60	No	No
				300.40	DYSTHMIA X 7YRS	60	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
McGrath	111057	Week 8	2	799.90	DEFERRED	60	No	No
	111058	Screen	1	296.2X	MAJOR DEPRESSION, SINGLE EP, ATYPICAL	50	Yes	Yes
			2	799.90	DEFERRED	50	Yes	Yes
			3	851.80	H/O COMA X4 DAYS 1994	50	Yes	Yes
		Week 8	1	296.3	MAJOR DEPRESSION	60	No	Yes
	111171	Screen	1	296.20	NONE; MAJOR DEPRESSION (NON ATYPICAL, NON MELANCHOLIC)	60	No	Yes
				300.40	DYSTHYMIA	60	No	Yes
				307.51	BINGE EATING DISORDER	60	No	Yes
			2	799.90	DEFERRED	60	No	Yes
			3	307.05	OBESITY	60	No	Yes
		Week 8	1	296.20	MAJOR DEPRESSION, (NON-ATYPICAL, NON-MELANCHOLIC)	60	No	Yes
				300.40	DYSTHYMIA	60	No	Yes
				307.51	BINGE EATING DISORDER	60	No	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
McGrath	111171	Week 8	2	799.90	DEFERRED	60	No	Yes
			3	307.05	OBESITY	60	No	Yes
Moreines	121007	Screen	1	296.33	ATYPICAL	38	No	No
			3	394.90	OTHER + UNSPECIFIED-MITRAL VALVE (PROLAPSE) DISEASE	38	No	No
		Week 8	1	296.36	ATYPICAL (MAJOR DEPRESSION) IN FULL REMISSION	72	No	No
			3	394.90	OTHER & UNSPECIFIED MITRAL VALVE (PROLAPSE) DISEASE	72	No	No
		Week 32/Final	1	296.32	ATYPICAL MAJOR DEPRESSION RECURRENT; MODERATE WITHOUT PSYCHOTIC FEATURES	38	No	No
			3	394.90	OTHER + UNSPECIFIED MITRAL VALVE DISEASE	38	No	No
Munjack	131011	Screen	1	296.2X	MAJOR DEPRESSIVE DISORDER,MIXED EPISODE	53	No	No
			3	272.0	HYPERCHOLESTEROLEMIA (ESSENTIAL)	53	No	No
		Week 8	1	296.21	MAJOR DEPRESSION-SINGLE EPISODE, MIXED, MILD	73	No	No
			3	272.0	HYPERCHOLESTEROLEMIA/ESSENTIAL	73	No	No
		Week 32/Final	3	272.0	HYPERCHOLESTEROLEMIA	87	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Munjack	131012	Screen	1	296.3X	MDD, RECURRENT, MELANCHOLIC	59	No	No
				300.02	GAD	59	No	No
	131071	Screen	1	296.33	MDD, RECURRENT, MELANCHOLIC TYPE	50	No	No
	131072	Screen	1	296.32	MDD, RECURRENT, MELANCHOLIC TYPE	59	No	No
			3	493.90	ASTHMA BRONCHIALE	59	No	No
		Week 8	1	296.32	MELANCHOLIC TYPE	65	No	No
			3	493.90	ASTHMA BRONCHIALE	65	No	No
	131125	Screen	1	296.22	MELANCHOLIC TYPE	50	No	No
				307.51	PAST HISTORY (NONE SINCE 3/99) BULIMIA NERVOSA	50	No	No
		Week 8	1	296.21	NONE	68	No	No
		Week 32/Final	1	296.21	NONE	68	No	No
	131126	Screen	1	296.22	MELANCHOLIC	59	No	No
	131143	Screen	1	296.23	MELANCHOLIC TYPE	50	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Munjack	131143	Week 8	1	296.21	MELANCHOLIC	87	No	No
	131144	Screen	1	296.22	MELANCHOLIC TYPE	58	No	No
		Week 8	1	296.22	MELANCHOLIC TYPE	60	No	No
Nelson	141041	Screen	1	296.32	MAJOR DEPRESSION, RECURRENT	65	No	Yes
			3	401.09	HYPERTENSION, HYPERCHOLESTEROLEMIA, URINARY INCONT.	65	No	Yes
		Week 8	1	296.35	MIXED	65	Yes	No
Oldroyd	321055	Screen	1	296.23	MAJOR DEPRESSION, SEVERE, SINGLE EPISODE MELANCHOLIC TYPE	35	No	No
	321056	Screen	1	296.33	MAJOR DEPRESSION, RECURRENT, SEVERE INTENSITY WITH MELANCHOLIC FEATURE	45	No	No
		Week 8	1	296.33	MAJOR DEPRESSION, RECURRENT WITH MELANCHOLIC FEATURE	45	No	No
	321087	Screen	1	296.32	MAJOR DEPRESSION, RECURRENT, MODERATE INTENSITY WITH MELANCHOLIC FEATURES	55	No	No
			3	070.10	H/O HEPATITIS A (DX:1968)	55	No	No
				365.90	GLAUCOMA	55	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Oldroyd	321087	Week 8	1	296.35	MAJOR DEPRESSION, RECURRENT, PARTIAL REMISSION, WITHOUT MELANCHOLIA	70	No	No
			3	070.10	HEPATITIS A (DIAGNOSED @1968)	70	No	No
				365.90	GLAUCOMA	70	No	No
		Week 32/Final	1	296.35	MAJOR DEPRESSION, MELANCHOLIC,RECURRENT, PARTIAL REMISSION	80	No	No
			3	070.10	HISTORY OF HEPATITIS A. (DIAGNOSIS @ 1968)	80	No	No
				365.90	GLAUCOMA (STABLE)	80	No	No
Prover	261023	Screen	1	296.30	MELANCHOLIC	65	No	No
		Week 8	1	296.20	MAJOR DEPRESSION (MELANCHOLIC)	75	Yes	No
			3	599.89	UTI, CLEARED	75	Yes	No
Rapaport	151037	Screen	1	296.32	MELANCHOLIC; MAJOR DEPRESSION, RECURRENT, MODERATE	45	Yes	No
			2	799.90	DEFERRED	45	Yes	No
			3	799.90	DEFERRED	45	Yes	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151037	Week 8	1	296.32	MAJOR DEPRESSION, RECURRENT, MODERATE; MELANCHOLIC	52	No	No
			2	799.90	DEFERRED	52	No	No
			3	799.90	DEFERRED	52	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	50	No	No
			2	799.90	DEFERRED	50	No	No
			3	799.90	DEFERRED	50	No	No
	151038	Screen	1	296.32	MAJOR DEPRESSION DISORDER, RECURRENT, MODERATE, MELANCHOLIC	50	No	No
			2	799.90	DEFERRED	50	No	No
			3	799.90	DEFERRED	50	No	No
		Week 8	1	296.32	MELANCHOLIC	50	No	No
			2	799.90	DEFERRED	50	No	No
			3	799.90	DEFERRED	50	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	45	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151038	Week 32/Final	2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
	151085	Screen	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE, MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
	151086	Screen	1	296.32	MAJOR DEPRESSION, RECURRENT, MODERATE, MELANCHOLIC	40	No	No
			2	799.90	DEFERRED	40	No	No
			3	799.90	DEFERRED	40	No	No
		Week 8	1	296.32	MELANCHOLIC	45	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151086	Week 8	2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
	151095	Screen	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE, MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	60	No	No
			2	799.90	DEFERRED	60	No	No
			3	799.90	DEFERRED	60	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	50	No	No
			2	799.90	DEFERRED	50	No	No
			3	799.90	DEFERRED	50	No	No
	151096	Screen	1	296.32	MAJOR DEPRESSION, RECURRENT, MODERATE, MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151096	Screen	3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	60	No	No
			2	799.90	DEFERRED	60	No	No
			3	799.90	DEFERRED	60	No	No
		Week 32/Final	1	296.32	MELANCHOLIC	40	No	No
			2	799.90	DEFERRED	40	No	No
			3	799.90	DEFERRED	40	No	No
	151099	Screen	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	60	No	No
			2	799.90	DEFERRED	60	No	No
			3	799.90	DEFERRED	60	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151099	Week 32/Final	1	296.32	MELANCHOLIC	40	No	No
			2	799.90	DEFERRED	40	No	No
			3	799.90	DEFERRED	40	No	No
	151100	Screen	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
	151117	Screen	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	50	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151117	Week 8	2	799.90	DEFERRED	50	No	No
			3	799.90	DEFERRED	50	No	No
	151118	Screen	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
		Week 8	1	296.32	MELANCHOLIC	45	No	No
			2	799.90	DEFERRED	45	No	No
			3	799.90	DEFERRED	45	No	No
	151153	Screen	1	296.32	MELANCHOLIC	40	No	No
			2	799.90	DEFERRED	40	No	No
			3	799.9	DEFERRED	40	No	No
		Week 8	1	296.32	MELANCHOLIC	40	No	No
			2	799.90	DEFERRED	40	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Rapaport	151153	Week 8	3	799.90	DEFERRED	40	No	No
Smith	281025	Screen	1	296.33	MAJOR DEPRESSIVE DISORDER, RECURRENT SEVERE, MELANCHOLIC	50	No	No
			2	V71.09	NO DIAGNOSIS	50	No	No
			3	555.90	CROHNS DISEASE IN REMISSION	50	No	No
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVERE	30	No	No
			2	V71.09	NO DX	30	No	No
			3	V71.09	CHROHN'S DZ, IN REMISSION	30	No	No
	281026	Screen	1	296.33	WITH MELANCHOLIC FEATURES; MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE, SEVERE	40	Yes	No
			2	V71.09	NO DIAGNOSIS	40	Yes	No
			3	V71.09	NO DIAGNOSIS	40	Yes	No
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER SINGLE EPISODE, SEVERE WITH MELANCHOLIC FEATURES	40	Yes	No
			2	V71.09	NO DISGNOSIS	40	Yes	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Smith	281026	Week 8	3	V71.09	NO DIAGNOSIS	40	Yes	No
	281101	Screen	1	296.22	MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE, MODERATE, CHRONIC WITH MELANCHOLIC FEATURES	50	No	No
			2	V71.09	NO DX	50	No	No
			3	VV71.09	NO DIAGNOSIS	50	No	No
		Week 8	1	296.22	MAJOR DEPRESSIVE DISORDER, SINGLE EPISODE, MODERATE, CHRONIC, WITH MELANCHOLIC FEATURES	50	No	No
			2	V71.09	NO DX	50	No	No
			3	V71.09	NO DX	50	No	No
	281102	Screen	1	296.33	MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVERE, WITHOUT MELANCHOLIC FEATURES, MIXED	50	No	No
			2	V71.09	NO DIAGNOSIS	50	No	No
			3	333.99	RESTLESS LEGS SYNDROME	50	No	No
				795.50	HISTORY OF POSITIVE PPD	50	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Smith	281102	Week 8	1	296.31	MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVERE, WITHOUT MELANCHOLIC FEATURES, MIXED	80	No	No
			2	V71.09	NO DIAGNOSIS	80	No	No
			3	333.99	RESTLESS LEGS SYNDROME	80	No	No
				795.50	HISTORY OF POSITIVE PPD	80	No	No
		Week 32/Final	1	296.33	MAJOR DEPRESSIVE DISORDER, RECURRENT, SEVER WITH MELANCHOLIC FEATURES	40	No	No
			2	V71.09	NO DIAGNOSIS	40	No	No
			3	333.99	RESTLESS LEGS SYNDROME	40	No	No
				795.50	PAST HISTORY OF POSITIVE PPD	40	No	No
	281107	Screen	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE, CHRONIC WITHOUT MELANCHOLIC FEATURES MIXED	50	No	No
			2	V71.09	NO DIAGNOSIS	50	No	No
			3	242.80	HYPOTHYROIDISM, CORRECTED	50	No	No
				530.81	GASTROESOPHAGAEL REFLUX DISEASE	50	No	No

LIST5

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Smith	281107	Week 8	1	296.32	MAJOR DEPRESSIVE DISORDER, RECURRENT, MODERATE, CHRONIC, WITHOUT MELANCHOLIC FEATURES, MIXED	50	No	No
			2	V71.09	NO DIAGNOSIS	50	No	No
			3	242.80	HYPOTHYROIDISM, CORRECTED	50	No	No
				530.81	GASTROESOPHAGEAL REFLUX DISEASE	50	No	No
	281108	Screen	1	296.33	MAJOR DEPRESSIVE DISORDER,RECURRENT, SEVERE, WITH ATYPICAL FEATURES	40	No	Yes
			2	V71.09	NO DIAGNOSIS	40	No	Yes
			3	276.80	HYPERKALEMIA, CORRECTED	40	No	Yes
				401.00	HYPERTENSION	40	No	Yes
		Week 8	1	296.33	MAJOR DEPRESSIVE DISORDER, RECURRENT SEVERE WITH ATYPICAL FEATURES, IN REMISSION	90	No	No
			2	V71.09	NO DX	90	No	No
			3	276.80	HYPOKALEMIA, CORRECTED	90	No	No
				401.00	HYPERTENSION	90	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Smith	281108	Week 32/Final	1	296.32	MAJOR DEPRESSIVE, RECURRENT, MIXED, WITH MELANCHOLIC FEATURES	40	No	No
			2	V71.09	NO DIAGNOSIS	40	No	No
			3	276.80	HYPOKALEMIA	40	No	No
				401.00	HTN	40	No	No
Telew	171016	Screen	1	296.22	NONE	45	No	No
				300.04	DYSTHYMIC DISORDER	45	No	No
				303.09	ALCOHOL DEPENDENCE WITH SUSTAINED FULL REMISSION	45	No	No
			3	474.00	TONSILLITIS	45	No	No
				540.00	APPENDICITIS	45	No	No
	171027	Screen	1	296.32	NONE	45	No	No
				300.02	GENERALIZED ANXIETY DISORDER	45	No	No
				300.40	DYSTHYMIC DISORDER	45	No	No
			3	614.90	PELVIC INFLAMMATORY DISEASE	45	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Telew	171027	Screen	3	627.20	MENOPAUSE	45	No	No
		Week 8	1	296.32	NONE	45	No	No
				300.02	GENERALIZED ANXIETY DISORDER	45	No	No
				300.40	DYSTHYMIC DISORDER	45	No	No
			3	614.90	PELVIC INFLAMMATORY DISEASE	45	No	No
				627.20	MENOPAUSE	45	No	No
Thase	181083	Screen	1	296.32	MELANCHOLIC	55	Yes	Yes
		Week 32/Final	1	296.35	NO OTHER SPECIFIER	80	No	No
	181084	Screen	1	296.32	MIXED	58	No	No
			2	V71.09	NO DIAGNOSIS ON AXIS II	58	No	No
		Week 8	1	296.35	MIXED	85	No	No
			2	V71.09	DEFERRED	85	No	No
		Week 32/Final	1	296.32	MIXED	60	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Thase	181084	Week 32/Final	2	V71.09	NO DIAGNOSIS ON AXIS II	60	No	No
	181105	Screen	1	296.22	MELANCHOLIC	60	No	No
		Week 8	1	296.22	NONE	60	No	No
			2	799.90	DEFERRED	60	No	No
			3	473.90	RECURRENT SINUSITIS	60	No	No
				625.30	DYSMENORRHEA	60	No	No
	181106	Screen	1	296.22	WITH MELANCHOLIC FEATURES	58	No	No
	181135	Screen	1	296.32	MELANCHOLIC	65	No	No
	181136	Screen	1	296.22	NONE	57	No	No
				300.29	SPECIFIC PHOBIA	57	No	No
		Week 8	1	296.25	NONE	72	No	No
Trivedi	191013	Screen	1	296.22	MIXED	54	No	No
		Week 8	1	296.22	MIXED	54	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Trivedi	191014	Screen	1	296.32	MELANCHOLIC TYPE	58	No	Yes
		Week 8	1	296.35	MELANCHOLIC TYPE	75	No	No
Walsh	171015	Screen	1	296.22	NONE	50	No	No
				300.40	DYSTHYMIC DISORDER	50	No	No
				303.90	ALCOHOL DEPENDENCE WITH SUSTAINED FULL REMISSION	50	No	No
			3	401.90	HYPERTENSION	50	No	No
		Week 8	1	296.22	NONE	50	No	No
				300.40	DYSTHYMIC DISORDER	50	No	No
				303.90	ALCOHOL DEPENDENCE WITH SUSTAINED FULL REMISSION	50	No	No
			3	401.90	HYPERTENSION	50	No	No
		Week 32/Final	1	296.22	NONE	50	No	No
				300.40	DYSTHYMIC DISORDER	50	No	No
				303.90	ALCOHOL DEPENDENCE, WITH SUSTAINED FULL REMISSION	50	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Walsh	171015	Week 32/Final	3	401.90	HYPERTENSION	50	No	No
	171028	Screen	1	296.32	CHRONIC	55	No	No
				300.40	DYSTHYMIC DISORDER	55	No	No
				305.00	ALCOHOL ABUSE-REMISSION	55	No	No
				307.51	BULIMIA NERVOSA-REMISSION	55	No	No
			3	577.00	HISTORY OF PANCREATITIS	55	No	No
		Week 8	1	296.32	CHRONIC	55	No	No
				300.40	DYSTHYMIC DISORDER	55	No	No
				305.00	ALCOHOL ABUSE-REMISSION	55	No	No
				307.51	BULIMIA NEROSA-REMISSION	55	No	No
			3	577.00	HISTORY OF PANCREATITIS	55	No	No
	171061	Screen	1	296.23	NONE	55	No	No
				300.40	DYSTHYMIC DISORDER	55	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Walsh	171061	Week 8	1	296.23	NONE	55	No	No
				300.40	DYSTHEMIC DISORDER	55	No	No
	171062	Screen	1	296.23	NONE	55	Yes	Yes
		Week 8	1	296.23	NONE	85	Yes	Yes
		Week 32/Final	1	296.23	NONE	55	Yes	Yes
	171063	Screen	1	296.25	NONE	55	No	No
				305.00	ALCOHOL ABUSE-IN REMISSION	55	No	No
		Week 8	1	296.25	NONE	65	No	No
				305.00	ALCOHOL ABUSE - IN REMISSION	65	No	No
		Week 32/Final	1	296.25	NONE	55	No	No
				305.00	ALCOHOL ABUSE-IN REMISSION	55	No	No
	171064	Screen	1	296.35	NONE	50	No	No
		Week 8	1	296.35	NONE	72	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Zajecka	201067	Screen	1	296.3	MAJOR DEPRESSION D/O, RECURRENT WITH ATYPICAL FEATURES	60	No	No
			2	799.9	DEFERRED	60	No	No
		Week 8	1	296.31	MAJOR DEPRESSIVE DISORDER	65	No	Yes
			2	799.90	DEFERRED	65	No	Yes
		Week 32/Final	1	296.3	ATYPICAL FEATURE	85	No	No
			2	799.9	DEFERRED	85	No	No
	201068	Screen	1	276.30	WITH ATYPICAL FEATURES; MAJOR DEPRESSIVE D/O, RECURRENT	55	No	No
			2	V71.09	NO DIAGNOSIS	55	No	No
			3	401.9	HYPERTENSION, ESSENTIAL	55	No	No
		Week 8	1	296.30	ATYPICAL FEATURES	70	No	No
			2	V71.09	NO DIAGNOSIS	70	No	No
			3	401.9	HYPERTENSION (ESSENTIAL)	70	No	No
		Week 32/Final	1	296.30	MAJOR DEPRESSIVE %, RECURRENT WITH ATYPICAL FEATURES	55	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Zajecka	201068	Week 32/Final	2	V71.09	NO DIAGNOSIS	55	No	No
			3	401.9	HTN, ESSENTIAL	55	No	No
	201091	Screen	1	296.3	WITH MELANCHOLIC FEATURE	60	No	No
			2	V71.09	NO DIAGNOSIS	60	No	No
			3	473.90	ASTHMA-STABLE	60	No	No
				535.50	GASTRITIS-STABLE	60	No	No
	201092	Screen	1	296.32	MELANCHOLIC FEATURES	41	No	No
			2	V71.09	NO DIAGNOSIS	41	No	No
		Week 8	1	296.32	MELANCHOLIC FEATURES	80	No	No
			2	V71.09	NO DIAGNOSIS	80	No	No
	201123	Screen	1	296.32	MELANCHOLIC FEATURES	55	No	No
			2	V71.09	NO DIAGNOSIS	55	No	No
		Week 8	1	296.32	MELANCHOLIC FEATURES	70	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV 5-Axis Clinical Diagnosis - Listing by Patient

All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Axis 1-3	Code	Name	Axis V Score	Mood Reactivity	Rejection Sensitivity
Zajecka	201123	Week 8	2	V71.09	NO DIAGNOSIS	70	No	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Amsterdam	11134	Screen	Occupational Problems	
			Problems with Access to Health Care Services	
		Week 8	Occupational Problems	
			Economic Problems	
			Problems with Access to Health Care Services	
Barbee	21053	Screen	Educational Problems	
		Week 8	Educational Problems	
Clayton	31019	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	
			Problems with Access to Health Care Services	
		Week 8	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Clayton	31019	Week 8	Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	
			Problems with Access to Health Care Services	
		Week 32/Final	Occupational Problems	
			Housing Problems	
			Problems with Access to Health Care Services	
	31020	Screen	Occupational Problems	
		Week 8	Occupational Problems	
		Week 32/Final	Occupational Problems	
	31047	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
	31048	Screen	Occupational Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Croft	231001	Screen	Problems with Primary Support Group	
		Week 32/Final	Problems with Primary Support Group	
	231002	Week 8	Other Psychosocial and Environment Problems: MEDICAL PROBLEMS	
	231080	Screen	Occupational Problems	
		Week 8	Occupational Problems	
DuBoff	311017	Week 8	Occupational Problems	
	311018	Screen	Problems with Primary Support Group	
			Economic Problems	
			Problems with Access to Health Care Services	
		Week 8	Problems with Primary Support Group	
			Economic Problems	
			Problems with Access to Health Care Services	
	311116	Screen	Problems Related to The Social Environment	MENTAL ABUSE BY EX-HUSBAND

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Dunner	211039	Screen	Occupational Problems	
		Week 8	Occupational Problems	
			Economic Problems	
	211040	Screen	Occupational Problems	
			Economic Problems	
		Week 8	Economic Problems	
		Week 32/Final	Economic Problems	
	211110	Screen	Occupational Problems	
			Problems Related to Interaction with Legal System/ Crime	
		Week 8	Occupational Problems	
			Problems Related to Interaction with Legal System/ Crime	
		Week 32/Final	Problems Related to Interaction with Legal System/ Crime	SELLING MO'S HOUSE; LAW SUIT EMPLOYEE FILED AGAINST HER

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Dunner	211110	Week 32/Final	Other Psychosocial and Environment Problems: .	SELLING MO'S HOUSE; LAW SUIT EMPLOYEE FILED AGAINST HER
	211145	Screen	Economic Problems	
	211146	Screen	Occupational Problems	
			Other Psychosocial and Environment Problems: SPOUSE	
		Week 8	Other Psychosocial and Environment Problems: WIFE SEVERELY DEPRESSED	
	211147	Screen	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	
Fava	51113	Screen	Occupational Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Fava	51113	Week 8	Occupational Problems	
	51114	Screen	Problems with Primary Support Group	
			Economic Problems	
			Other Psychosocial and Environment Problems: LOSS OF JOB, LACK OF FAMILY SUPPORT	
	51141	Screen	Economic Problems	
		Week 8	Economic Problems	
	51142	Screen	Problems with Primary Support Group	
			Occupational Problems	
Ferguson	241032	Screen	Problems with Primary Support Group	
			Economic Problems	
			Other Psychosocial and Environment Problems: DIVORCE & FINANCIAL PROBLEMS	
	241073	Screen	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Ferguson	241073	Screen	Other Psychosocial and Environment Problems: FAMILY CONFLICT	
		Week 8	Problems with Primary Support Group	MILD FAMILY CONFLICT
	241074	Screen	Housing Problems	LIVING WITH IN LAWS/FINANCIAL PROBLEM
			Economic Problems	LIVING WITH IN LAWS/FINANCIAL PROBLEM
		Week 8	Problems with Primary Support Group	MOVE IN WITH IN LAWS, FINANCIAL PROBLEMS
			Economic Problems	MOVE IN WITH IN LAWS, FINANCIAL PROBLEMS
Gilmer	61081	Screen	Problems Related to The Social Environment	
		Week 8	Problems Related to The Social Environment	
Halbreich	71077	Screen	Occupational Problems	
Helfing	81003	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
			Housing Problems	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Helfing	81004	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
	81051	Screen	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	
			Other Psychosocial and Environment Problems: NEW MOVE	
	81052	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Educational Problems	
			Occupational Problems	
			Housing Problems	
			Economic Problems	
			Problems with Access to Health Care Services	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Helfing	81052	Screen	Problems Related to Interaction with Legal System/ Crime	
			Other Psychosocial and Environment Problems: CUSTODY ISSUES	
		Week 8	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Educational Problems	
			Occupational Problems	
			Housing Problems	
			Economic Problems	
			Problems with Access to Health Care Services	
			Problems Related to Interaction with Legal System/ Crime	
			Other Psychosocial and Environment Problems: .	
	81075	Screen	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Helfing	81075	Screen	Problems Related to The Social Environment	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
		Week 32/Final	Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	
	81076	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Helfing	81076	Week 32/Final	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Economic Problems	
	81103	Screen	Problems Related to The Social Environment	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
			Housing Problems	
			Economic Problems	
		Week 32/Final	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Housing Problems	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Hoopes	271021	Screen	Problems Related to The Social Environment	
			Economic Problems	
		Week 8	Problems Related to The Social Environment	
			Economic Problems	
	271022	Screen	Problems Related to The Social Environment	
			Occupational Problems	
		Week 8	Problems Related to The Social Environment	
			Occupational Problems	
		Week 32/Final	Problems Related to The Social Environment	
			Occupational Problems	
	271045	Screen	Problems Related to The Social Environment	
		Week 8	Problems Related to The Social Environment	
Liebowitz	91005	Screen	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Liebowitz	91005	Week 8	Problems with Primary Support Group	
	91006	Screen	Problems Related to The Social Environment	
			Problems with Access to Health Care Services	
		Week 8	Problems with Primary Support Group	
			Economic Problems	
			Problems with Access to Health Care Services	
	91036	Screen	Problems with Access to Health Care Services	
	91097	Screen	Problems with Primary Support Group	
	91098	Screen	Problems with Primary Support Group	
			Economic Problems	
			Problems with Access to Health Care Services	
		Week 8	Occupational Problems	
			Housing Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Liebowitz	91098	Week 8	Problems with Access to Health Care Services	
	91138	Screen	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	
		Week 8	Economic Problems	
Londborg	101009	Screen	Economic Problems	
		Week 8	Economic Problems	
	101010	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Economic Problems	

LIST6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Londborg	101043	Screen	Economic Problems	
			Other Psychosocial and Environment Problems: STRESS OF 4 CHILDREN	
Lydiard	221033	Screen	Other Psychosocial and Environment Problems: X-WIFE IS A COCAINE ADICT	
		Week 8	Occupational Problems	
	221034	Screen	Problems with Primary Support Group	
	221129	Screen	Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	
		Week 8	Economic Problems	
McGrath	111057	Screen	Problems with Access to Health Care Services	
	111058	Screen	Problems with Primary Support Group	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
McGrath	111171	Screen	Occupational Problems	
		Week 8	Occupational Problems	
Moreines	121007	Screen	Occupational Problems	
			Economic Problems	
		Week 8	Occupational Problems	
			Economic Problems	
		Week 32/Final	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	
Munjack	131011	Screen	Problems with Primary Support Group	STRESSFUL JOB; FINANCIALLY "TIGHT"
			Occupational Problems	STRESSFUL JOB; FINANCIALLY "TIGHT"
			Economic Problems	STRESSFUL JOB; FINANCIALLY "TIGHT"
			Other Psychosocial and Environment Problems: PROBLEMS W/ WIFE SECONDARY TO DECREASED LIBIDO;	STRESSFUL JOB; FINANCIALLY "TIGHT"

LIST6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Munjack	131011	Week 8	Occupational Problems	
			Economic Problems	
			Other Psychosocial and Environment Problems: FINANCIAL DIFFICULTIES, HIGH STRESS LEVEL AT JOB	
	131012	Screen	Problems with Primary Support Group	CARRIER PROGRESS, FINANCIAL DIFFICULTIES
			Occupational Problems	CARRIER PROGRESS, FINANCIAL DIFFICULTIES
			Economic Problems	CARRIER PROGRESS, FINANCIAL DIFFICULTIES
			Other Psychosocial and Environment Problems: LIVING ALONE - LONELY	CARRIER PROGRESS, FINANCIAL DIFFICULTIES
		Week 8	Problems with Primary Support Group	LIVES ALONE; STRESS ON THE JOB; FINANCIAL DIFFICULTIES
			Occupational Problems	LIVES ALONE; STRESS ON THE JOB; FINANCIAL DIFFICULTIES
			Economic Problems	LIVES ALONE; STRESS ON THE JOB; FINANCIAL DIFFICULTIES
	131071	Screen	Problems with Primary Support Group	FINANCIAL PROBLEMS
			Economic Problems	FINANCIAL PROBLEMS

LIST6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Munjack	131071	Screen	Other Psychosocial and Environment Problems: ISOLATED BY FAMILY	FINANCIAL PROBLEMS
	131072	Screen	Problems with Primary Support Group	SEPARATED FROM FAMILY TODAY; NOT WORKING CURRENTLY
			Occupational Problems	SEPARATED FROM FAMILY TODAY; NOT WORKING CURRENTLY
			Economic Problems	SEPARATED FROM FAMILY TODAY; NOT WORKING CURRENTLY
			Other Psychosocial and Environment Problems: FINANCIAL STRESS	SEPARATED FROM FAMILY TODAY; NOT WORKING CURRENTLY
		Week 8	Problems with Primary Support Group	SEPARATED FROM FAMILY; NOT WORKING CURRENTLY
			Occupational Problems	SEPARATED FROM FAMILY; NOT WORKING CURRENTLY
			Economic Problems	SEPARATED FROM FAMILY; NOT WORKING CURRENTLY
	131125	Screen	Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	
		Week 8	Occupational Problems	

LIST6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Munjack	131125	Week 32/Final	Occupational Problems	JOB STRESS
	131126	Screen	Occupational Problems	TIED WITH FINANCES
			Economic Problems	TIED WITH FINANCES
			Other Psychosocial and Environment Problems: STRESSFUL WORK;	TIED WITH FINANCES
		Week 8	Occupational Problems	STRESSFUL JOB
			Economic Problems	STRESSFUL JOB
			Other Psychosocial and Environment Problems: FINANCIAL DIFFICULTIES	STRESSFUL JOB
	131143	Screen	Problems with Primary Support Group	STRESSFUL RELATIONSHIP; FINANCIAL DIFFICULTIES
			Economic Problems	STRESSFUL RELATIONSHIP; FINANCIAL DIFFICULTIES
			Other Psychosocial and Environment Problems: HUSBAND WITH MDD,	STRESSFUL RELATIONSHIP; FINANCIAL DIFFICULTIES
		Week 8	Problems with Primary Support Group	STRESSFUL RELATIONSHIP, FINANCIAL DIFFICULTIES
			Economic Problems	STRESSFUL RELATIONSHIP, FINANCIAL DIFFICULTIES

LIST6

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Munjack	131143	Week 8	Other Psychosocial and Environment Problems: HUSBAND WITH MDD	STRESSFUL RELATIONSHIP, FINANCIAL DIFFICULTIES
	131144	Screen	Educational Problems	FINANCIAL DIFFICULTIES
			Economic Problems	FINANCIAL DIFFICULTIES
			Other Psychosocial and Environment Problems: STRESS AT GRADUATE SCHOOL;	FINANCIAL DIFFICULTIES
		Week 8	Educational Problems	SCHOOL, FINANCIAL DIFFICULTIES
			Economic Problems	SCHOOL, FINANCIAL DIFFICULTIES
Nelson	141041	Screen	Occupational Problems	
		Week 8	Problems Related to The Social Environment	
Oldroyd	321055	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
			Occupational Problems	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Oldroyd	321056	Screen	Occupational Problems	
		Week 8	Occupational Problems	
	321087	Screen	Problems with Primary Support Group	
		Week 8	Problems Related to The Social Environment	
			Economic Problems	
		Week 32/Final	Problems with Primary Support Group	
Prover	261023	Screen	Problems with Primary Support Group	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
Rapaport	151037	Screen	Problems Related to The Social Environment	
		Week 8	Problems Related to The Social Environment	
		Week 32/Final	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Rapaport	151038	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
		Week 32/Final	Problems with Primary Support Group	
			Occupational Problems	
	151085	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
		Week 8	Problems with Primary Support Group	
	151086	Screen	Problems with Primary Support Group	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
	151095	Screen	Problems with Primary Support Group	
			Occupational Problems	
			Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Rapaport	151095	Week 8	Problems with Primary Support Group	
		Week 32/Final	Problems with Primary Support Group	
	151096	Screen	Problems with Primary Support Group	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
		Week 32/Final	Problems with Primary Support Group	
	151099	Screen	Problems with Primary Support Group	
			Problems Related to The Social Environment	
		Week 8	Problems with Primary Support Group	
		Week 32/Final	Problems with Primary Support Group	
	151100	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
	151117	Screen	Problems with Primary Support Group	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Rapaport	151117	Week 8	Problems with Primary Support Group	
			Occupational Problems	
	151118	Screen	Problems with Primary Support Group	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
			Housing Problems	
	151153	Screen	Problems with Primary Support Group	
		Week 8	Problems with Primary Support Group	
Smith	281025	Screen	Problems Related to The Social Environment	
		Week 8	Problems Related to The Social Environment	
	281026	Screen	Occupational Problems	
			Other Psychosocial and Environment Problems: UNHAPPY WITH JOB	
		Week 8	Occupational Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Smith	281101	Screen	Other Psychosocial and Environment Problems: FAILURE OF DEPRESSION TO LIFT	
		Week 8	Problems with Primary Support Group	
	281102	Screen	Other Psychosocial and Environment Problems: CHRONIC RECURRENT DEPRESSION THAT IS DEMORALIZING	
		Week 32/Final	Other Psychosocial and Environment Problems: CHRONIC DEPRESSION	
	281107	Screen	Other Psychosocial and Environment Problems: DEMORALIZATION OF DEPRESS	
		Week 8	Other Psychosocial and Environment Problems: DEMORALIZATION OF DEPRESSION	
	281108	Screen	Problems Related to The Social Environment	
			Economic Problems	
		Week 32/Final	Other Psychosocial and Environment Problems: PHYSICAL PAIN	
Telew	171016	Screen	Economic Problems	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Telew	171027	Screen	Problems with Primary Support Group	
			Problems with Access to Health Care Services	
		Week 8	Problems with Primary Support Group	
			Problems with Access to Health Care Services	
Thase	181083	Screen	Occupational Problems	
		Week 32/Final	Occupational Problems	
	181084	Screen	Occupational Problems	
	181105	Screen	Problems with Primary Support Group	
			Other Psychosocial and Environment Problems: WT GAIN	
		Week 8	Problems with Primary Support Group	
	181106	Screen	Problems with Primary Support Group	
			Educational Problems	
			Problems with Access to Health Care Services	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Thase	181135	Screen	Problems with Primary Support Group	
			Occupational Problems	
	181136	Screen	Problems with Primary Support Group	
			Occupational Problems	
Trivedi	191013	Screen	Problems with Primary Support Group	
			Economic Problems	
		Week 8	Problems with Primary Support Group	
			Economic Problems	
Walsh	171015	Screen	Economic Problems	
		Week 8	Economic Problems	
		Week 32/Final	Economic Problems	
	171028	Screen	Other Psychosocial and Environment Problems: PSYCHOSOCIAL STRESSORS: MILD CHRONIC	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Walsh	171028	Week 8	Other Psychosocial and Environment Problems: PSYCHOSOCIA STRESSORS	
	171061	Screen	Problems with Primary Support Group	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
	171062	Screen	Problems with Primary Support Group	
			Occupational Problems	
		Week 8	Problems with Primary Support Group	
			Occupational Problems	
		Week 32/Final	Problems with Primary Support Group	
			Occupational Problems	
	171063	Screen	Other Psychosocial and Environment Problems: PHYSICAL COMPLAINTS	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Walsh	171063	Week 8	Other Psychosocial and Environment Problems: PHYSICAL COMPLAINTS	
		Week 32/Final	Other Psychosocial and Environment Problems: PHYSICAL COMPLAINTS	
	171064	Screen	Other Psychosocial and Environment Problems: BREAK UP WITH BOYFRIEND	
		Week 8	Other Psychosocial and Environment Problems: BREAK UP WITH BOYFRIEND	
Zajecka	201067	Screen	Problems with Primary Support Group	PROBLEMS AT WORK
			Occupational Problems	PROBLEMS AT WORK
			Other Psychosocial and Environment Problems: NEW BABY	PROBLEMS AT WORK
		Week 8	Problems with Primary Support Group	
			Problems Related to The Social Environment	
		Week 32/Final	Problems with Primary Support Group	WORK ENVIRONMENT PROBLEM
			Occupational Problems	WORK ENVIRONMENT PROBLEM

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

DSM-IV: Axis IV Diagnosis - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Problems	Comment
Zajecka	201067	Week 32/Final	Other Psychosocial and Environment Problems: NEW BABY	WORK ENVIRONMENT PROBLEM
	201068	Screen	Other Psychosocial and Environment Problems: IN ESTRANGED RELATIONSHIP	
		Week 8	Other Psychosocial and Environment Problems: ???	
		Week 32/Final	Other Psychosocial and Environment Problems: IN ESTRANGED RELATIONSHIP	
	201091	Screen	Occupational Problems	POOR MUSCLE JOB SATISFACTION
	201092	Screen	Occupational Problems	NOT WORKING BECAUSE OF ILLNESS
			Economic Problems	NOT WORKING BECAUSE OF ILLNESS
		Week 8	Housing Problems	NOT WORKING BECAUSE OF ILLNESS
			Economic Problems	NOT WORKING BECAUSE OF ILLNESS
	201123	Screen	Occupational Problems	POOR CONCENTRATION AT WORK
		Week 8	Occupational Problems	POOR CONCENTRATION

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
11065	59/Male	RBX	Digestive	GINGIVITIS	GINGIVITIS	44	21	28	Moderate	No	Recovered	None	No
			Urogenital	IMPOTENCE	IMPOTENCE	44	1		Moderate	No	Not recovered	None	Yes
				URINATION IMPAIRED	URINARY HESITANCY	44	1	13	Moderate	No	Recovered	None	No
				DISORDER URETHRAL	URINARY DISCHARGE	44	1	13	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	44	1	13	Mild	No	Recovered	None	Yes
11066	56/Male	RBX	Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	80	15		Moderate	No	Not recovered	None	Yes
			Respiratory	SINUSITIS	SINUSITIS	80	17	29	Moderate	No	Recovered	None	No
			Nervous	INSOMNIA	MIDDLE INSOMNIA	80	57		Moderate	No	Not recovered	None	Yes
			Body	ABDOMINAL PAIN LOCALIZED	STOMACH PAIN	80	68		Moderate	No	Not recovered	None	Yes
				CHILLS	COLD SENSATION IN FINGERTIPS	80	0		Mild	No	Not recovered	None	Yes
11133	41/Male	RBX	Skin	HERPES ZOSTER	SHINGLES	64	-14	25	Severe	No	Recovered	None	No
			Body	CHILLS	UPPER BODY FEEL COLD	64	1	24	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING	64	1	24	Moderate	No	Recovered	None	No

Note: * Treatment refers to the treatment assigned in the blinded medication phase. This information might not be relevant if the AE started and stopped before the end of open phase of the study.
Day of last dose, onset day and stop day are all relative to baseline day.

LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
11133	41/Male	RBX	Urogenital	URGENCY URINATION	URINARY URGENCY	64	1	12	Mild	No	Recovered	None	No
			Body	FATIGUE	DAYTIME FATIGUE	64	1	22	Moderate	No	Recovered	None	No
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	64	1	8	Mild	No	Recovered	None	No
			Respiratory	SINUSITIS	SINUS INFECTION	64	3	29	Moderate	No	Recovered	None	No
			Cardiovascular	HYPOTENSION	LOW BLOOD PRESSURE	64	14	26	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	LIGHT HEADED	64	16	29	Moderate	No	Recovered	Drug temporar-ily withdrawn	No
					DIZZY	64	17	29	Moderate	No	Recovered	Drug temporar-ily withdrawn	No
			Body	FEVER	FEVER	64	17	19	Moderate	No	Recovered	Drug temporar-ily withdrawn	Yes
			Cardiovascular	HYPOTENSION POSTUR-AL	ORTHOSTATIC HYPOTENSION	64	12	27	Moderate	No	Recovered	None	No
			Respiratory	CONGESTION CHEST	CHEST CONGESTION	64	46		Mild	No	Not recovered	None	No
			Cardiovascular	DISORDER PERIPHERAL VASCULAR	HANDS FEEL COLD	64	1	24	Moderate	No	Recovered	None	No

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
11134	49/Male	RBX	Digestive	HEMORRHOID	INCREASE IN RECTAL BLEEDING DUE TO HEMORRHOIDS	60	8		Mild	No	Not recovered	None	No
			Urogenital	EJACULATION ABNORM-AL	PREMATURE EJACULA-TION	60	31		Mild	No	Not recovered	None	Yes
			Cardiovascular	TACHYCARDIA	INCREASED PULSE (IN EVENING)	60	6		Mild	No	Not recovered	None	No
11159	48/Female	RBX	Special Senses	BLURRED VISION	BLURRED VISION	58	9	43	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA (INTERMITT-ENT)	58	16		Mild	No	Not recovered	None	Yes
			Body	NON-GENERALIZED WEAKNESS NOS	WEAKNESS IN ARMS	58	27	28	Mild	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	58	0		Moderate	No	Not recovered	None	No
			Special Senses	EAR PAIN	EARACHE	58	49		Moderate	No	Not recovered	None	No
11160	61/Male	RBX	Digestive	CONSTIPATION	CONSTIPATION	56	6		Moderate	No	Not recovered	None	Yes
			Nervous	ANXIETY	JITTERINESS	56	1	12	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	INCREASED SWEATING	56	1	12	Severe	No	Recovered	None	No

Note: * Treatment refers to the treatment assigned in the blinded medication phase. This information might not be relevant if the AE started and stopped before the end of open phase of the study.
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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
11160	61/Male	RBX	Body	ABDOMINAL DISTENSI-ON	BLOATED	56	1		Moderate	No	Not recovered	None	No
			Urogenital	DYSURIA	INCREASE PRESSURE DURING URINATION	56	2	26	Moderate	No	Recovered	None	No
				URGENCY URINATION	INCREASED URINARY URGENCY	56	2	26	Moderate	No	Recovered	None	No
				DYSURIA	BURNING DURING URINATION	56	2	26	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING	56	31		Mild	No	Not recovered	None	No
11167	53/Female	RBX	Cardiovascular	VASODILATION	HOT FLASHES	61	-19		Moderate	No	Not recovered	None	No
21053	30/Male	RBX	Urogenital	URINATION IMPAIRED	URINARY HESITANCY	50	2		Mild	No	Not recovered	None	Yes
			Digestive	GASTROENTERITIS	INTESTINAL VIRUS	50	4	6	Moderate	No	Recovered	Drug temporar-ily withdrawn	No
			Body	ENVIRONMENTAL ALLERGY	HAYFEVER	50	13	14	Moderate	No	Recovered	None	No
				LOCALIZED PAIN	PAIN IN ARM (LEFT)	50	13	16	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	INCREASED DRY MOUTH	50	12		Mild	No	Not recovered	None	Yes

Note: * Treatment refers to the treatment assigned in the blinded medication phase. This information might not be relevant if the AE started and stopped before the end of open phase of the study.
Day of last dose, onset day and stop day are all relative to baseline day.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
21053	30/Male	RBX	Body	ENVIRONMENTAL ALLERGY	HAYFEVER	50	27	31	Moderate	No	Recovered	None	No
			Nervous	NERVOUSNESS	IRRITABILITY	50	21		Moderate	No	Not recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	50	25	27	Mild	No	Recovered	None	Yes
			Special Senses	TASTE PERVERSION	METALLIC TASTE	50	25		Mild	No	Not recovered	None	Yes
			Digestive	DYSPEPSIA	HEARTBURN	50	25	34	Moderate	No	Recovered	None	Yes
			Body	BACK PAIN	MUSCLE PAIN - BACK	50	34	34	Mild	No	Recovered	None	No
			Digestive	DYSPEPSIA	HEARTBURN	50	48	48	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	50	47	47	Moderate	No	Recovered	None	Yes
			Nervous	EMOTIONAL LABILITY	MOOD LABILITY	50	37		Mild	No	Not recovered	None	Yes
31019	45/Male	RBX	Digestive	DYSPEPSIA	ACID INDIGESTION	85	2	6	Severe	No	Recovered	None	Yes
							8		Moderate	No	Not recovered	None	No
			Respiratory	SINUSITIS	SINUS CONGESTION	85	28		Mild	No	Not recovered	None	No
31020	55/Male	Placebo	Nervous	INSOMNIA	INSOMNIA	225	3		Mild	No	Not recovered	None	No
			Body	HEADACHE	HEADACHE	225	0	224	Mild	No	Recovered	None	No

Note: * Treatment refers to the treatment assigned in the blinded medication phase. This information might not be relevant if the AE started and stopped before the end of open phase of the study.
Day of last dose, onset day and stop day are all relative to baseline day.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
31020	55/Male	Placebo	Body	BACK PAIN	LOW BACK PAIN	225	31	34	Mild	No	Recovered	None	No
				LOCALIZED PAIN	LEG PAIN	225	31	34	Mild	No	Recovered	None	No
				UPPER RESPIRATORY INFECTION	HEAD COLD	225	39	43	Moderate	No	Recovered	None	No
31047	27/Female	RBX	Nervous	INSOMNIA	INSOMNIA	56	0		Moderate	No	Not recovered	None	No
31048	46/Female	Placebo	Body	HEADACHE	HEADACHE	72	1		Mild	No	Not recovered	None	No
			Urogenital	DYSMENORRHEA	MENSTRUAL CRAMPS	72	22	22	Moderate	No	Recovered	None	No
31111	37/Female	RBX	Nervous	INSOMNIA	INSOMNIA	19	0	7	Mild	No	Recovered	None	No
			Respiratory	BRONCHITIS	BRONCHITIS	19	8	11	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	LIGHTHEADEDNESS	19	15	17	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	19	15	17	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	19	15	17	Mild	No	Recovered	None	Yes
			Digestive	VOMITING	VOMITING	19	17	17	Mild	No	Recovered	None	Yes
			Respiratory	BRONCHITIS	BRONCHITIS	19	21		Moderate	No	Not recovered	None	No
31112	44/Female	RBX	Body	BACK PAIN	BACK ACHE	60	5	5	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
31112	44/Female	RBX	Digestive	CONSTIPATION	CONSTIPATION	60	1	29	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	60	0	59	Moderate	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	60	0	0	Mild	No	Recovered	None	Yes
			Cardiovascular	PALPITATION	HEART RACING	60	0	0	Mild	No	Recovered	None	Yes
			Body	ENVIRONMENTAL ALLERGY	SEASONAL ALLERGIES	60	39	43	Moderate	No	Recovered	None	No
			Respiratory	SINUSITIS	SINUSITIS	60	44	53	Moderate	No	Recovered	None	No
41069	41/Female	RBX	Digestive	APPETITE INCREASED	INCREASED APPETITE	71		37	Severe	No	Recovered	None	No
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	71		37	Severe	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	71	1	37	Moderate	No	Recovered	None	No
				NERVOUSNESS	IRRITABILITY	71	1	51	Severe	No	Recovered	None	Yes
				CONCENTRATION IMPAIRED	DIFFICULTY CONCEN-TRATING	71	1		Moderate	No	Not recovered	None	No
				PARASOMNIA NOS	BRUXISM	71	1	37	Moderate	No	Recovered	None	No
				ANXIETY	ANXIETY	71	1		Moderate	No	Not recovered	None	Yes

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41069	41/Female	RBX	Digestive	CONSTIPATION	CONSTIPATION	71	15	22	Moderate	No	Recovered	None	Yes
			Nervous	HYPERTONIA	MUSCLE TENSION	71	15		Mild	No	Not recovered	None	Yes
			Body	TRAUMA	CUT WRIST (ACCIDE-NTAL)	71	8		Moderate	No	Not recovered	None	No
			Respiratory	SINUSITIS	SINUS INFECTION	71	37	53	Severe	No	Recovered	None	No
			Metabolic and Nutritional	PERIPHERAL EDEMA	BILATERAL ANKLE EDEMA	71	63		Mild	No	Not recovered	None	Yes
			Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	JOINT PAIN (BILAT-ERAL WRIST)	71	58		Mild	No	Not recovered	None	Yes
			Body	FEVER	FEVER	71	61	61	Mild	No	Recovered	None	No
			Musculo-Skeletal	ARTHRALGIA SINGLE AND MULTIPLE JOINT	BILATERAL KNEE JOINT PAIN	71	58		Mild	No	Not recovered	None	Yes
					BILATERAL ANKLE JOINT PAIN	71	58		Mild	No	Not recovered	None	Yes
			Skin	ERYTHEMA	3 REDDENED PATCHES OF SKIN RIGHT LOWER EXTREMITY	71	57		Mild	No	Not recovered	None	Yes

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Adverse Events - Listing by Patient
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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
41069	41/Female	RBX	Skin	ERYTHEMA	2 REDDENED PATCHES OF SKIN ON LEFT LOWER EXTREMITY	71	57		Mild	No	Not recovered	None	Yes
41070	46/Female	RBX	Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	63	-826	52	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	63			Severe	No	Not recovered	None	Yes
			Body	CHILLS	COLD SENSATIONS	63	1	1	Mild	No	Recovered	None	Yes
				HEADACHE	HEADACHES	63	2	2	Moderate	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	HEARTBURN	63	2		Mild	No	Not recovered	None	No
				CONSTIPATION	CONSTIPATION	63	6	14	Moderate	No	Recovered	None	Yes
			Body	CHEST PAIN	CHEST PRESSURE	63	15	17	Moderate	No	Recovered	None	No
			Cardiovascular	PALPITATION	PALPITATIONS	63	15	17	Moderate	No	Recovered	None	Yes
			Body	BACK PAIN	BACK PAIN	63	33	35	Moderate	No	Recovered	None	No
			Special Senses	BLURRED VISION	BLURRED VISION	63	0		Moderate	No	Not recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	63	1	2	Mild	No	Recovered	None	Yes
							4	4	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
41070	46/Female	RBX	Cardiovascular	VASODILATION	HOT FLASHES	63	6	6	Mild	No	Recovered	None	Yes
							12	12	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	63	4	4	Moderate	No	Recovered	None	Yes
							20	21	Moderate	No	Recovered	None	Yes
					HEADACHE	63	30	31	Moderate	No	Recovered	None	Yes
							46	46	Moderate	No	Recovered	None	Yes
					HEADACHES	63	54	54	Moderate	No	Recovered	None	Yes
				CHILLS	COLD SENSATIONS	63	4	4	Mild	No	Recovered	None	Yes
							6	6	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	63	0	0	Mild	No	Recovered	None	Yes
							19	19	Mild	No	Recovered	None	Yes
			Nervous	PARESTHESIA	TINGLING SENSATION IN SCALP	63	0	0	Mild	No	Recovered	None	Yes
					TINGLING SENSATION IN LEFT ARM	63	34	34	Mild	No	Recovered	None	Yes
			Digestive	GASTROENTERITIS	GASTROENTERITIS	63	45	45	Mild	No	Recovered	None	Yes

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Adverse Events - Listing by Patient
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Date Produced: January 15, 2001

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41070	46/Female	RBX	Digestive	ULCER MOUTH	SORES IN ROOF OF MOUTH	63	4	8	Mild	No	Recovered	None	Yes
			Body	NON-GENERALIZED WEAKNESS NOS	SENSATION OF WEAKNESS IN ARMS	63	55	55	Mild	No	Recovered	None	Yes
				REACTION UNEVALUAB-LE	SENSATION OF HEAVINESS IN LEGS	63	10	11	Mild	No	Recovered	None	Yes
				NON-GENERALIZED	WEAKNESS IN LEGS	63	4	4	Mild	No	Recovered	None	Yes
				WEAKNESS NOS			55	55	Mild	No	Recovered	None	Yes
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	63	10	10	Mild	No	Recovered	None	Yes
							25	25	Mild	No	Recovered	None	Yes
							43	43	Mild	No	Recovered	None	Yes
			Skin	PRURITUS NON-	ITCHY SCALP	63	0	2	Mild	No	Recovered	None	Yes
				APPLICATION SITE			4	4	Mild	No	Recovered	None	Yes
							9	9	Mild	No	Recovered	None	Yes
							12	12	Mild	No	Recovered	None	Yes
41093	56/Female	RBX	Digestive	GASTROESOPHAGEAL REFLUX	ACID REFLUX	72	-44	1	Mild	No	Recovered	None	No

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Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
41093	56/Female	RBX	Nervous	APATHY	EMOTIONAL BLUNTING	72	-14	18	Moderate	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	72	-2	0	Moderate	No	Recovered	None	No
				DRY MOUTH	DRY MOUTH	72	2	6	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	DIAPHORETIC	72	3	5	Mild	No	Recovered	None	No
			Body	FLU SYNDROME	FLU SYMPTOMS	72	8	13	Moderate	No	Recovered	None	No
			Respiratory	DYSPNEA	DIFFICULTY BREATH-ING (ASTHMA)	72	21	26	Mild	No	Recovered	None	No
			Nervous	CONFUSION	CONFUSION	72	61	62	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	DIAPHORETIC	72	9	9	Mild	No	Recovered	None	No
							12	13	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	72	44	44	Mild	No	Recovered	None	Yes
			Nervous	CONFUSION	CONFUSION	72	56	56	Moderate	No	Recovered	None	Yes
			Skin	PRURITUS NON-APPLICATION SITE	ITCHY MOUTH	72	28	28	Mild	No	Recovered	None	Yes
			Body	REACTION UNEVALUAB-LE	SENSATION OF HEAVINESS IN LEGS	72	56	56	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
41093	56/Female	RBX	Body	FATIGUE	FATIGUE	72	31	31	Mild	No	Recovered	None	No
							34	35	Mild	No	Recovered	None	No
							43	43	Mild	No	Recovered	None	No
							49	49	Mild	No	Recovered	None	No
							54	54	Mild	No	Recovered	None	No
							56	56	Mild	No	Recovered	None	No
							60	60	Mild	No	Recovered	None	No
							63	67	Mild	No	Recovered	None	No
							26	26	Mild	No	Recovered	None	No
			Skin	NODULE SKIN	NODULE SUBCUTANEO-US (L. THUMB)	72	34		Mild	No	Not recovered	None	No
			Body	FATIGUE	FATIGUE	72	31	31	Mild	No	Recovered	None	No
							34	35	Mild	No	Recovered	None	No
							40	40	Mild	No	Recovered	Dose increased	No
							28	28	Mild	No	Recovered	None	No

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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
41094	64/Female	RBX	Nervous	ANXIETY	ANXIETY	70	-28	46	Severe	No	Recovered	None	Yes
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	70		24	Moderate	No	Recovered	None	No
			Body	UPPER RESPIRATORY INFECTION	URI	70	4	20	Severe	No	Recovered	None	No
				LOCALIZED PAIN	LEG ACHE	70	19	53	Mild	No	Recovered	None	No
			Digestive	DYSPEPSIA	HEARTBURN	70	8	8	Mild	No	Recovered	None	Yes
51113	55/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	58	4		Mild	No	Not recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	58	4	29	Mild	No	Recovered	None	Yes
			Urogenital	BREAST PAIN	BREAST TENDERNESS	58	2	40	Mild	No	Recovered	None	No
			Nervous	MUSCLE CRAMP	NOCTURNAL CRAMPS	58	16	17	Mild	No	Recovered	None	No
			Body	TRAUMA	RIB INJURY	58	-11	38	Mild	No	Recovered	None	No
			Nervous	AKATHISIA	AKATHESIA	58	31	44	Mild	No	Recovered	None	No
				MUSCLE CRAMP	CRAMPS IN FEET	58	55	55	Mild	No	Recovered	None	No
							56	56	Mild	No	Recovered	None	No

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Adverse Events - Listing by Patient
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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
51114	54/Female	RBX	Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	37	10	19	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	37	10	12	Moderate	No	Recovered	None	No
51141	30/Female	RBX	Nervous	SUICIDAL TENDENCY	INCREASE IN SUICIDAL IDEATION	58	3	21	Severe	No	Recovered	None	No
			Body	ABDOMINAL CRAMP	STOMACH CRAMPS	58	13	19	Mild	No	Recovered	None	No
			Nervous	NIGHTMARES	NIGHTMARES	58	7		Moderate	No	Not recovered	None	Yes
				HYPERTONIA	BODY SPASMS	58		18	Mild	No	Recovered	None	No
			Body	REACTION UNEVALUAB-LE	TEMPERATURE SENSITIVITY	58	0	6	Mild	No	Recovered	None	Yes
51142	44/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	56	-126		Moderate	No	Not recovered	None	Yes
			Body	LOCALIZED PAIN	PAIN IN RIGHT HEEL	56	14	24	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHES	56	-126	1	Mild	No	Recovered	None	No
			Nervous	HYPERTONIA	BODY SPASMS	56		1	Mild	No	Recovered	None	No
				INSOMNIA	INSOMNIA	56	-126	1	Mild	No	Recovered	None	No
				SOMNOLENCE	DROWSINESS	56	-126	1	Mild	No	Recovered	None	No

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All Enrolled Patients

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
61081	45/Female	RBX	Nervous	DIZZINESS	DIZZINESS	5	0		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Body	CHILLS	CHILLS	5	0	6	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
			Nervous	SOMNOLENCE	DROWSINESS	5	0	6	Severe	No	Recovered	Drug permanen-tly withdrawn	Yes
			Digestive	CONSTIPATION	CONSTIPATION	5	0		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Cardiovascular	VASODILATION	FEELING FLUSHED	5	0	6	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
			Nervous	ATAXIA	ATAXIA	5	7		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
61082	56/Female	RBX	Digestive	NAUSEA	NAUSEA	6	1		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPS	6	2		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Skin	DIAPHORETIC	SWEATING	6	0		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Body	CHILLS	CHILLS	6	2		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
61082	56/Female	RBX	Nervous	INSOMNIA	INSOMNIA	6	0		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
				MANIC SYMPTOMS	RACING THOUGHTS	6	3		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
71077	56/Female	RBX	Nervous	INSOMNIA	INSOMNIA	64	2		Moderate	No	Not recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	64	2	41	Moderate	No	Recovered	None	Yes
				CONSTIPATION	CONSTIPATION	64	2		Moderate	No	Not recovered	None	Yes
				DRY MOUTH	DRY MOUTH	64	2		Moderate	No	Not recovered	None	Yes
			Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD HANDS	64	2		Moderate	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	64	14	14	Moderate	No	Recovered	None	Yes
			Nervous	NIGHTMARES	VIOLENT DREAMS	64	61		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
81003	65/Female	Placebo	Body	HEADACHE	TENSION HEADACHE	64	29	54	Moderate	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	EARLY SATIETY	64	4		Mild	No	Not recovered	None	Yes
			Nervous	ANXIETY	JITTERYNESS	64	4	4	Mild	No	Recovered	None	Yes
				SOMNOLENCE	AM GROGGINESS	64	29		Moderate	No	Not recovered	None	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81003	65/Female	Placebo	Digestive	DRY MOUTH	DRY MOUTH	64	37		Moderate	No	Not recovered	None	Yes
				CONSTIPATION	CONSTIPATION	64	39		Moderate	No	Not recovered	None	Yes
				DRY MOUTH	DRY MOUTH	64	-19	0	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	64	2	4	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	64	2	4	Mild	No	Recovered	None	Yes
			Nervous	ANXIETY	INCREASED ANXIETY LEVEL	64	7	7	Moderate	No	Recovered	None	No
			Body	HEADACHE	TENSION HEADACHE	64	3	4	Moderate	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	64	8	8	Mild	No	Recovered	None	Yes
			Body	ABDOMINAL CRAMP	ABDOMINAL CRAMPS	64	12	12	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	64	8		Mild	No	Not recovered	None	Yes
			Special Senses	EYE IRRITATION	ITCHY EYES	64	14	27	Mild	No	Recovered	None	Yes
			Body	ABDOMINAL DISTENSI-ON	BLOATED	64	14		Mild	No	Not recovered	None	No
				ABDOMINAL PAIN GENERALIZED	ABDOMINAL PAIN	64	20	30	Mild	No	Recovered	None	No

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81003	65/Female	Placebo	Nervous	SOMNOLENCE	LETHARGY	64	42		Moderate	No	Not recovered	Dose reduced	Yes
			Respiratory	BRONCHITIS	BRONCHITIS	64	43		Mild	No	Not recovered	None	No
			Body	TRAUMA	FALL	64	53	69	Mild	No	Recovered	None	No
				ABDOMINAL CRAMP	ABDOMINAL CRAMPING	64	39		Moderate	No	Not recovered	None	Yes
			Digestive	FLATULENCE	GAS	64	14		Mild	No	Not recovered	None	No
			Body	ABDOMINAL PAIN GENERALIZED	ABDOMINAL PAIN	64	31		Moderate	No	Not recovered	None	No
81004	43/Female	Placebo	Urogenital	URINATION IMPAIRED	URINARY HESITANCY	78	3	7	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	78	3	62	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	78	0	5	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	78	13	13	Mild	No	Recovered	None	Yes
							22	22	Mild	No	Recovered	None	Yes
							28	29	Mild	No	Recovered	None	Yes
				TRAUMA	FINGER LACERATION	78	29	29	Mild	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	78	13	62	Moderate	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81004	43/Female	Placebo	Body	HEADACHE	HEADACHE	78	38	38	Mild	No	Recovered	None	Yes
							40	40	Mild	No	Recovered	None	Yes
			Cardiovascular	MIGRAINE	MIGRAINE HEADACHE	78	46	47	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	78	49	49	Mild	No	Recovered	None	Yes
							53	54	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	78	6		Moderate	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	78	56	56	Mild	No	Recovered	None	Yes
							58	58	Mild	No	Recovered	None	Yes
							66	66	Mild	No	Recovered	None	Yes
							69	69	Mild	No	Recovered	None	Yes
							75	75	Mild	No	Recovered	None	Yes
81051	37/Female	RBX	Nervous	DIZZINESS	DIZZINESS	26	1		Moderate	No	Not recovered	None	No
			Skin	DIAPHORETIC	COLD SWEATS	26	2		Moderate	No	Not recovered	None	Yes
			Body	ASTHENIA	DECREASED EXERTIONAL ENDURANCE	26	1		Moderate	No	Not recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81051	37/Female	RBX	Digestive	CONSTIPATION	CONSTIPATION	26	7		Mild	No	Not recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRED VISION	26	7		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	26	2	3	Mild	No	Recovered	None	Yes
			Nervous	NERVOUSNESS	INCREASED IRRITAB-ILITY	26	8		Moderate	No	Not recovered	None	Yes
			Skin	HAIR LOSS	HAIR LOSS	26	26		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
				ECZEMA	INCREASED ECZEMA	26	26		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Body	ALLERGIC REACTION	ALLERGIC REACTION TO YARD	26	15		Mild	No	Not recovered	None	No
			Digestive	GASTROINTESTINAL BLEEDING	BLEEDING BOWEL	26	23		Moderate	No	Not recovered	None	No
				NAUSEA	NAUSEA	26	21		Moderate	No	Not recovered	None	Yes
81052	39/Female	RBX	Body	HEADACHE	HEADACHE	20	1	28	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	INCREASED SWEATING WITH PILOERECTION	20	0	28	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	20	1	28	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81052	39/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	20	-15	28	Mild	No	Recovered	None	No
			Nervous	DRUG DEPENDENCE	ALCOHOL RELAPSE	20	9	17	Severe	Yes	Recovered	None	No
				DEPRESSIVE SYMPTOMS	WORSENING OF DEPRESSION	20	9	17	Severe	No	Recovered	None	No
81075	37/Female	RBX	Nervous	SOMNILOQUISM	SLEEP TALKING	167	2	166	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	167	5	5	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	167	0	1	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	167	0	1	Mild	No	Recovered	None	Yes
			Cardiovascular	TACHYCARDIA	INCREASED HEART RATE	167	0	1	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	167	11	67	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	167	14	26	Moderate	No	Recovered	None	Yes
							33	33	Moderate	No	Recovered	None	No
				TRAUMA	MOTOR VEHICLE ACCIDENT	167	33	33	Moderate	No	Recovered	None	No
			Cardiovascular	HYPERTENSION	INCREASED BLOOD PRESSURE	167	33	33	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81075	37/Female	RBX	Nervous	HYPERTONIA	NECK,SHOULDER AND BACK STIFFNESS	167	33	36	Moderate	No	Recovered	None	No
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	167	46	47	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	167	50	50	Mild	No	Recovered	None	Yes
				FLU SYNDROME	FLU SYMPTOMS	167	82	83	Moderate	No	Recovered	None	No
			Cardiovascular	VASODILATION	FLUSHING	167	34	105	Mild	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	167	109	112	Moderate	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	167	14	70	Moderate	No	Recovered	None	Yes
			Cardiovascular	HYPERTENSION	INCREASED BLOOD PRESSURE	167	166		Mild	No	Not recovered	None	Yes
81076	23/Female	RBX	Respiratory	PHARYNGITIS	STREP THROAT	171	-4	13	Moderate	No	Recovered	None	No
			Body	GENERALIZED PAIN	BODY ACHES	171	-4	13	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED PERSPIR-ATION	171	0	34	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	171	12	78	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81076	23/Female	RBX	Nervous	HYPERTONIA	BACK SPASMS	171	14	16	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHES	171	17	21	Mild	No	Recovered	None	Yes
				BACK PAIN	BACK PAIN	171	25	25	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHE	171	36	36	Mild	No	Recovered	None	No
							32	42	Moderate	No	Recovered	None	Yes
				UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	171	45	57	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	171	61	61	Moderate	No	Recovered	None	Yes
				UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	171	63	65	Mild	No	Recovered	None	No
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	171			Mild	No	Not recovered	None	No
			Digestive	GASTROENTERITIS	VIRAL GASTROENTER-ITIS	171	81	85	Moderate	No	Recovered	None	No
			Musculo-Skeletal	DISORDER JOINT	DISLOCATED 2 RIBS - LEFT SIDE	171	98	133	Moderate	No	Recovered	None	No
			Digestive	GUM INFECTION	GUM INFECTION	171	135	140	Moderate	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
81103	48/Female	Placebo	Nervous	INSOMNIA	INSOMNIA	71	0		Moderate	No	Not recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	71	0	15	Moderate	No	Recovered	None	Yes
				CONSTIPATION	CONSTIPATION	71	6		Moderate	No	Not recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	71	0		Mild	No	Not recovered	None	Yes
			Nervous	AGITATION	AGITATION	71	4	15	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	71	8	8	Mild	No	Recovered	None	Yes
							10	10	Mild	No	Recovered	None	Yes
							13	13	Mild	No	Recovered	None	Yes
				LOCALIZED PAIN	BACK OF LEGS ACHE	71	14		Moderate	No	Recovered	None	Yes
				UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	71	10	16	Mild	No	Recovered	None	No
			Nervous	AGITATION	AGITATION	71	28	29	Mild	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	71	42	49	Mild	No	Recovered	None	No
					VIRAL UPPER RESPIRATORY INFECTION	71	51	59	Moderate	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
91005	54/Female	RBX	Special Senses	DISORDER EYE	RAPID EYE MOVEMENT (EYE TWITCHING)	36	0	0	Mild	No	Recovered	None	No
			Nervous	PARESTHESIA	TINGLING IN FEET	36	0	0	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHES	36	3	3	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	36	3	27	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	LIGHTHEADEDNESS	36	4	4	Mild	No	Recovered	None	Yes
					DIZZINESS	36	3	3	Mild	No	Recovered	None	Yes
				ANXIETY	JITTERNESS	36	25	27	Mild	No	Recovered	None	Yes
			Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS	36	29	29	Mild	No	Recovered	None	No
91006	44/Female	RBX	Digestive	NAUSEA	NAUSEA	56	0	0	Mild	No	Recovered	None	No
			Nervous	SOMNOLENCE	HYPERSOMNIA	56	0	0	Mild	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	56	2	46	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	56	5	6	Moderate	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	56	0	0	Moderate	No	Recovered	None	No
			Body	HEADACHE	WORSENING OF HEADACHE	56	8	14	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
91006	44/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	56	15	46	Mild	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRY VISION	56	28	46	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HEAT FEELINGS (FLUSHING)	56	45		Mild	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	56	48		Mild	No	Not recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	56	8	36	Mild	No	Recovered	None	No
							49	50	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	56	48		Mild	No	Not recovered	None	Yes
			Body	LOCALIZED PAIN	BILATERAL LEG PAIN	56	47		Mild	No	Not recovered	None	Yes
91035	62/Female	RBX	Skin	DIAPHORETIC	INCREASED SWEATING OF FACE	57	-6		Mild	No	Not recovered	None	No
91036	38/Male	RBX	Nervous	ANXIETY	INCREASED ANXIETY	4	2		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes
				DEPRESSIVE SYMPTOMS	INCREASED DEPRESS-ION	4	2		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes
				INSOMNIA	SLEEPING DIFFICUL-TIES	4	2		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
91036	38/Male	RBX	Nervous	HOSTILITY	ANGRY MOOD	4	2		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes
91097	38/Female	RBX	Body	FATIGUE	FATIGUE	54	-44	26	Mild	No	Recovered	None	No
			Digestive	DYSPEPSIA	HEARTBURN	54	0	19	Moderate	No	Recovered	None	Yes
				DRY MOUTH	DRY MOUTH	54	1	7	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	54	13	15	Moderate	No	Recovered	None	No
			Nervous	TREMOR	TREMOR	54	13	13	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	54	13	14	Mild	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	54	6	31	Mild	No	Recovered	None	No
				DISORDER VULVOVAGI-NAL	VAGINAL REDNESS	54	19	21	Moderate	No	Recovered	None	No
				DYSURIA	DYSURIA	54	19	31	Severe	No	Recovered	None	No
				DISORDER MENSTRUAL NEC	DELAYED MENSES	54	14	22	Mild	No	Recovered	None	No
			Digestive	APPETITE INCREASED	INCREASED APPETITE	54	23		Moderate	No	Not recovered	None	Yes
				DRY MOUTH	DRY MOUTH	54	27		Mild	No	Not recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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91097	38/Female	RBX	Musculo-Skeletal	CARPAL TUNNEL SYNDROME	BILATERAL CARPAL TUNNEL SYNDROME	54	26		Moderate	No	Not recovered	None	No
			Skin	HERPES SIMPLEX DERM	GENITAL HERPES	54	35		Mild	No	Not recovered	None	No
91098	23/Female	RBX	Cardiovascular	HYPOTENSION POSTURAL	ORTHOSTATIC HYPOTENSION	7	5	8	Severe	No	Recovered	Drug permanently withdrawn	Yes
91137	40/Male	RBX	Body	FLU SYNDROME	FLU SYMPTOMS	57	2	25	Moderate	No	Recovered	None	No
			Cardiovascular	VASODILATION	HOT FLASH	57	-6	-6	Moderate	No	Recovered	None	No
			Nervous	ATAXIA	LOSS OF BALANCE	57	-6	-6	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	57	19	19	Moderate	No	Recovered	None	No
			Respiratory	RHINITIS	DRY NOSE	57	15	26	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	57	15	25	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	57	24	30	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	57	29		Mild	No	Not recovered	None	Yes
			Special Senses	DRY EYES	DRY EYES	57	31		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	57	35		Mild	No	Not recovered	None	Yes
				TRAUMA	FALL	57	-6	-6	Moderate	No	Recovered	None	No

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Adverse Events - Listing by Patient
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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
91137	40/Male	RBX	Body	TRAUMA	10 STITCHES ON HEAD	57	-6	-6	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	57	35		Mild	No	Not recovered	None	Yes
			Respiratory	RHINITIS	RUNNY NOSE	57	43		Mild	No	Not recovered	None	Yes
91138	45/Female	RBX	Body	UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	50	-5	11	Mild	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	50	2	15	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INITIAL INSOMNIA	50	16		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHES	50	30		Mild	No	Not recovered	None	Yes
101009	36/Female	RBX	Body	HEADACHE	HEADACHE	21	1	8	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	SOMNOLENCE	21	1		Moderate	No	Not recovered	None	Yes
				CONCENTRATION IMPAIRED	DECREASED CONCENT-RATION	21	15		Moderate	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	21	20		Mild	No	Not recovered	None	Yes
			Body	FATIGUE	DAYTIME FATIGUE	21	-185	2	Moderate	No	Recovered	None	No
101010	51/Female	RBX	Skin	DIAPHORETIC	INCREASED SWEATING	57	1		Mild	No	Not recovered	None	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
101010	51/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	57	1		Mild	No	Not recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	57	5		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	57	9	9	Mild	No	Recovered	None	Yes
			Nervous	CNS STIMULATION	CNS STIMULATION	57		17	Mild	No	Recovered	Drug permanen-tly withdrawn	No
				LIBIDO DECREASED	DECREASED LIBIDO	57			Mild	No	Not recovered	Drug permanen-tly withdrawn	No
			Cardiovascular	TACHYCARDIA	TACHYCARDIA	57	34	43	Mild	No	Recovered	None	Yes
				HYPERTENSION	ELEVATED BLOOD PRESSURE	57	56	63	Mild	No	Recovered	None	Yes
			Body	BACK PAIN	BACKACHE	57	37	38	Mild	No	Recovered	None	No
101043	31/Female	RBX	Nervous	INSOMNIA	EARLY MORNING AWAKENING (INSOMN-IA-LATE)	65	2	30	Mild	No	Recovered	None	Yes
			Respiratory	SINUSITIS	SINUS INFECTION	65	27	39	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	65	44	57	Mild	No	Recovered	None	Yes
101044	41/Female	Placebo	Skin	DIAPHORETIC	NIGHT SWEATS	211		50	Moderate	No	Recovered	None	No

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All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
101044	41/Female	Placebo	Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	211		0	Moderate	No	Recovered	None	No
			Nervous	CNS STIMULATION	CNS STIMULATION	211	1	10	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	211	1	50	Moderate	No	Recovered	None	Yes
			Digestive	TOOTHACHE	TOOTHACHE	211	33	33	Mild	No	Recovered	None	No
			Respiratory	RHINITIS	NASAL CONGESTION	211	36	36	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	211	57	60	Mild	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	VIRAL UPPER RESPIRATORY INFECTION	211	62	75	Mild	No	Recovered	None	No
				INFECTION FUNGAL NOS	YEAST INFECTION	211	65	80	Mild	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	211	83	83	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	211	7		Moderate	No	Not recovered	None	Yes
			Body	ABDOMINAL PAIN LOCALIZED	STOMACH PAIN	211	71	80	Mild	No	Recovered	None	Yes
			Digestive	TOOTHACHE	TOOTH ACHE	211	109	110	Mild	No	Recovered	None	No

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
101044	41/Female	Placebo	Body	UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	211	171	176	Mild	No	Recovered	None	No
			Respiratory	PHARYNGITIS	SORE THROAT	211	171	176	Mild	No	Recovered	None	No
			Urogenital	INFECTION URINARY TRACT	URINARY TRACT INFECTION	211	199	213	Mild	No	Recovered	None	No
111057	48/Male	RBX	Digestive	NAUSEA	NAUSEA	18	-36		Mild	No	Not recovered	None	No
				ERUCTATION	BELCHING	18	-36		Mild	No	Not recovered	None	No
			Body	HEADACHE	HEADACHE	18	0		Moderate	No	Not recovered	Dose reduced	Yes
			Urogenital	URINATION IMPAIRED	DIFFCULTY URINATI-NG	18	0		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
111058	20/Female	RBX	Digestive	APPETITE DECREASED	DECREASED APPETITE	58	1	1	Mild	No	Recovered	None	Yes
				DYSPEPSIA	UPSET BOWELS	58	2	2	Mild	No	Recovered	None	Yes
				NAUSEA	NAUSEA	58	3	3	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	TOO SLEEPY	58	4	4	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	58	5	5	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	TOO SLEEPY	58	6	6	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

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111058	20/Female	RBX	Digestive	CONSTIPATION	CONSTIPATION	58	17	17	Mild	No	Recovered	Drug temporar-ily withdrawn	Yes
				APPETITE INCREASED	INCREASED APPETITE	58	24	25	Mild	No	Recovered	None	Yes
							27	27	Mild	No	Recovered	None	Yes
							29	29	Mild	No	Recovered	None	Yes
							31	34	Mild	No	Recovered	None	Yes
							36	42	Severe	No	Recovered	None	Yes
							43	57	Moderate	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	SLEEPY	58	43	43	Mild	No	Recovered	None	Yes
							45	45	Mild	No	Recovered	None	Yes
							47	49	Mild	No	Recovered	None	Yes
111171	50/Male	RBX	Nervous	SOMNOLENCE	DROWSINESS	57	0	65	Moderate	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	57	1	65	Moderate	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	TROUBLE URINATING	57	1	65	Severe	No	Recovered	None	Yes
			Digestive	CONSTIPATION	MILD CONSTIPATION	57	2	23	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
111171	50/Male	RBX	Urogenital	EJACULATION ABNORM-AL	EJACULATORY DISCOMFORT	57	12	23	Mild	No	Recovered	None	Yes
121007	33/Female	RBX	Nervous	NERVOUSNESS	IRRITABILITY	93	1	20	Moderate	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	93	1	20	Moderate	No	Recovered	None	Yes
			Body	CHILLS	CHILLS	93	1	4	Mild	No	Recovered	None	Yes
				FATIGUE	INCREASED FATIGUE	93	1	19	Severe	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	93	3	75	Moderate	No	Recovered	None	Yes
				GASTROENTERITIS	FOOD POISONING	93	22	24	Moderate	No	Recovered	Drug temporar-ily withdrawn	No
			Skin	DIAPHORETIC	SWEATING	93	29	69	Moderate	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	DROWSINESS	93	1	21	Severe	No	Recovered	None	Yes
			Digestive	INCREASED THIRST	INCREASED THIRST	93	3	75	Moderate	No	Recovered	None	Yes
			Body	ASTHENIA	WEAKNESS	93	48	92	Moderate	No	Recovered	None	Yes
			Urogenital	PYELONEPHRITIS	KIDNEY INFECTION	93	58	77	Moderate	No	Recovered	None	No
			Skin	RASH	RASH ON LEFT ARM	93	38	42	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
121007	33/Female	RBX	Skin	PRURITUS NON-APPLICATION SITE	ITCHING ON L ARM	93	69	92	Mild	No	Recovered	None	Yes
			Nervous	NERVOUSNESS	IRRITABILITY	93	71		Severe	No	Not recovered	None	Yes
				DIZZINESS	DIZZINESS	93	38	92	Moderate	No	Recovered	None	Yes
131011	56/Male	Placebo	Body	HEADACHE	HEADACHE	198	2	2	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	198	53	62	Moderate	No	Recovered	None	Yes
							74	76	Mild	No	Recovered	None	Yes
			Musculo-Skeletal	DISORDER TENDON	INFLAMED LIGAMENT AT BASE OF MIDDLE FINGER - R HAND	198	80	82	Moderate	No	Recovered	None	No
			Respiratory	SINUSITIS	SINUS INFECTION	198	86	89	Moderate	No	Recovered	None	No
							97	97	Mild	No	Recovered	None	No
			Body	REACTION UNEVALUAB-LE	TRIGGER FINGER CORRECTIVE SURGERY	198		156	Severe	No	Recovered	None	No
			Musculo-Skeletal	MYALGIA	MYALAGIA - BACK	198	175	177	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	198	4	4	Severe	No	Recovered	None	No
			Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS	198	3	5	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
131011	56/Male	Placebo	Skin	DIAPHORETIC	SWEATING	198	6	13	Mild	No	Recovered	None	No
131012	42/Female	Placebo	Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS (AT NIGHT)	199	7	10	Mild	No	Recovered	None	No
			Cardiovascular	MIGRAINE	MIGRAINE HEADACHE	199	4	4	Severe	No	Recovered	None	No
			Digestive	DYSPEPSIA	UPSET STOMACH	199	8	10	Mild	No	Recovered	None	No
			Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS (AT NIGHT)	199	13	14	Mild	No	Recovered	None	No
			Body	HEADACHE	TENSION HEADACHE	199	54	55	Moderate	No	Recovered	None	No
					HEADACHE	199	61	63	Severe	No	Recovered	None	No
				UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	199	64	64	Moderate	No	Recovered	None	No
			Cardiovascular	MIGRAINE	MIGRAINE HEADACHE	199	82	82	Severe	No	Recovered	None	No
			Body	UPPER RESPIRATORY INFECTION	COLD SXS	199	78	78	Mild	No	Recovered	None	No
131071	25/Male	RBX	Body	CHILLS	CHILLS AFTER		7	20	Mild	No	Recovered	None	No
					DOSING		25	26	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
131071	25/Male	RBX	Digestive	GASTRITIS	MILD STOMACH IRRITATION		1	1	Mild	No	Recovered	None	No
				FLATULENCE	BOZBOZYGMI		33	35	Mild	No	Recovered	None	No
				NAUSEA	NAUSEA		33	33	Mild	No	Recovered	None	No
131125	34/Female	Placebo	Digestive	NAUSEA	NAUSEA	74	4	6	Severe	No	Recovered	None	Yes
				VOMITING	VOMITING	74	6	6	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	74	19	20	Severe	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	FLUSHING	74	19	27	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	NIGHT SWEATS	74	20	27	Moderate	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	74	20	21	Mild	No	Recovered	None	Yes
				DYSPEPSIA	HEARTBURN	74	21	22	Moderate	No	Recovered	None	Yes
				DRY MOUTH	DRY MOUTH	74	32		Mild	No	Not recovered	None	Yes
			Skin	DERMATITIS	DERMATITIS	74	31	64	Mild	No	Recovered	None	Yes
			Body	TRAUMA	ABRASIONS INSIDE MOUTH	74	8	64	Mild	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	74	37	37	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
131125	34/Female	Placebo	Nervous	CHANGE IN DREAMS	VIVID DREAMS	74	2	57	Moderate	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	74	57	57	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	74	57	57	Severe	No	Recovered	None	Yes
				PERIOPERATIVE EVENT	POST-OP PAIN (L) BREAST	74	66	68	Moderate	No	Recovered	None	No
131126	45/Male	RBX	Nervous	INSOMNIA	INCREASED INSOMNIA	57	0		Severe	No	Not recovered	None	Yes
131143	39/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	56	1	14	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA-INCREASED	56	1	5	Moderate	No	Recovered	None	Yes
			Special Senses	TASTE PERVERSION	METAL TASTE IN MOUTH	56	1	5	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	INCREASE SWEATING (LASTING 2-4 HOURS AFTER DOSING)	56	1	5	Moderate	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASE APPETITE	56	1	5	Moderate	No	Recovered	None	Yes
			Body	REACTION UNEVALUAB-LE	SPACY FEELING (LASTING 2-4 HOURS AFTER DOSING)	56	1	5	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
131143	39/Female	RBX	Body	BACK PAIN	BACK PAIN AT (R) SCAPULA	56	22	27	Moderate	No	Recovered	None	No
131144	33/Female	RBX	Respiratory	ASTHMA	ASTHMA BRONCHIALE-EXACERBATION	56	10	11	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	56	23	27	Mild	No	Recovered	None	Yes
			Body	TRAUMA	HEMATOMA ON LEFT HIP DUE TO SPIDER BITE	56	50	61	Moderate	No	Recovered	None	No
141041	55/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	57	0	7	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	57	0		Moderate	No	Not recovered	None	Yes
			Nervous	INSOMNIA	POOR SLEEP	57	0	14	Severe	No	Recovered	None	No
			Body	ASTHENIA	TIREDNESS	57	7	14	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	SWEATING	57	7	14	Mild	No	Recovered	None	Yes
			Special Senses	TINNITUS	RINGING IN EARS	57	7	21	Mild	No	Recovered	None	Yes
				TASTE PERVERSION	BAD TASTE IN MOUTH	57	7	21	Mild	No	Recovered	None	Yes
			Cardiovascular	PALPITATION	HEART BEATING FASTER ONE MOMENT	57	14	21	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
141041	55/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	57	42		Mild	No	Not recovered	None	Yes
151037	62/Female	Placebo	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	240			Mild	No	Not recovered	None	No
			Digestive	VOMITING	VOMITTING	240		29	Mild	No	Recovered	None	No
				APPETITE DECREASED	DECREASED APPETIT-IE	240	8	16	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	240	32	99	Mild	No	Recovered	None	No
				ABDOMINAL DISTENSI-ON	STOMACH BLOATING	240	28	36	Mild	No	Recovered	None	No
				NECK PAIN	NECK PAIN	240	60		Mild	No	Not recovered	None	No
			Respiratory	SINUSITIS	SINUS INFECTION	240	70	87	Moderate	No	Recovered	None	No
			Body	GENERALIZED EDEMA	EDEMA	240	73	99	Moderate	No	Recovered	None	No
				LOCALIZED PAIN	KNEE PROBLEMS (PAIN)	240	103	103	Moderate	No	Recovered	None	No
				ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	240	111	112	Mild	No	Recovered	None	No
			Special Senses	VISION ABNORMAL	VISUAL IMPAIRMENT (RIGHT EYE)	240	142		Moderate	No	Not recovered	None	No

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151037	62/Female	Placebo	Body	FLU SYNDROME	FLU	240	84	93	Mild	No	Recovered	None	No
151038	52/Male	Placebo	Nervous	SOMNOLENCE	DROWSINESS	141	-41	42	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	141	-41	21	Mild	No	Recovered	None	Yes
			Nervous	PARESTHESIA	PARESTHESIA	141	-41	0	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHES	141	0	42	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	141	7	21	Mild	No	Recovered	None	Yes
			Special Senses	DISORDER LACRIMATI-ON	WATERY EYES	141	7		Mild	No	Not recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	141	28		Mild	No	Not recovered	None	No
			Skin	RASH	RASH (HIP)	141	33		Mild	No	Not recovered	None	No
			Nervous	PARESTHESIA	HYPERSENSITIVITY - SCALP TINGLING	141	39	42	Mild	No	Recovered	None	Yes
			Body	BACK PAIN	BACKPAIN	141	44		Mild	No	Not recovered	None	No
				FLU SYNDROME	FLU	141	73	77	Mild	No	Recovered	None	No
			Urogenital	CARCINOMA BLADDER	CANCER (BLADDER)	141	106	120	Severe	Yes	Recovered	None	No

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Adverse Events - Listing by Patient
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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151038	52/Male	Placebo	Body	UPPER RESPIRATORY INFECTION	COLD	141	73	77	Mild	No	Recovered	None	No
151085	50/Female	RBX	Body	BACK PAIN	MUSCLE ACHE (BACK)	14	-2	13	Mild	No	Recovered	None	No
			Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	14			Mild	No	Not recovered	None	No
				SOMNOLENCE	DROWSINESS	14		7	Mild	No	Recovered	None	No
			Cardiovascular	PALPITATION	RACING HEART	14	0	7	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	14	0		Mild	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	14	0	3	Mild	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRED VISION	14	0		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Body	HEADACHE	HEADACHES	14	6	9	Mild	No	Recovered	None	Yes
151086	45/Female	RBX	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	38		2	Mild	No	Recovered	None	No
				TREMOR	SHAKING	38	-6	21	Mild	No	Recovered	None	No
				SOMNOLENCE	DROWSINESS	38		21	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	38	4		Mild	No	Not recovered	None	Yes
			Skin	RASH	RASH (ON BREAST)	38	5	12	Mild	No	Recovered	None	Yes

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151086	45/Female	RBX	Digestive	CONSTIPATION	CONSTIPATION	38	0		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Skin	RASH	RASH (ON WRIST)	38	16	35	Mild	No	Recovered	None	No
			Body	GENERALIZED EDEMA	EDEMA	38	29		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHE	38	29		Mild	No	Not recovered	None	No
151095	49/Male	RBX	Skin	DIAPHORETIC	NIGHT SWEATS	156		0	Mild	No	Recovered	None	No
			Special Senses	TINNITUS	TINITUS	156	1		Mild	No	Not recovered	None	Yes
			Urogenital	POLYURIA	POLYURIA (FREQUENT URINATION)	156	1	28	Mild	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	HEARTBURN	156	2		Mild	No	Not recovered	None	No
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	156	14	28	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	156	33		Mild	No	Not recovered	None	Yes
				FLU SYNDROME	FLU	156	46	58	Mild	No	Recovered	None	No
			Skin	RASH	RASH (ARM)	156	47	55	Mild	No	Recovered	None	No
			Body	GENERALIZED EDEMA	EDEMA	156	55	58	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151095	49/Male	RBX	Digestive	CONSTIPATION	CONSTIPATION	156	54	73	Mild	No	Recovered	None	Yes
			Body	GENERALIZED EDEMA	EDEMA	156	70		Mild	No	Not recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	156	54	73	Mild	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRED VISION	156	90	99	Mild	No	Recovered	None	Yes
			Nervous	PARESTHESIA	TINGLING (RIGHT SIDE OF FACE)	156	107		Mild	No	Not recovered	None	Yes
151096	60/Male	Placebo	Body	NECK RIGID	STIFF NECK	93	3	3	Mild	No	Recovered	None	No
			Cardiovascular	HYPOTENSION POSTUR-AL	ORTHOSTATIC HYPOTENSION	93	17	17	Moderate	No	Recovered	None	Yes
			Digestive	DIARRHEA	DIARRHEA	93	14	14	Mild	No	Recovered	None	No
			Urogenital	IMPOTENCE	ERECTILE DYSFUNCT-ION	93	13	56	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	93	24	24	Mild	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	DELAYED URINATION	93	27	66	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	93	51	51	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	93	47	86	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151099	52/Female	Placebo	Nervous	LIBIDO DECREASED	LOSS OF LIBIDO	77	-96	41	Mild	No	Recovered	None	No
				SOMNOLENCE	DROWSINESS	77		13	Mild	No	Recovered	None	No
				TREMOR	SHAKING	77	-96	8	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	77	0	8	Mild	No	Recovered	None	Yes
			Body	ABDOMINAL DISTENSI-ON	BLOATING	77	1		Mild	No	Not recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	77	1	70	Mild	No	Recovered	None	Yes
			Respiratory	PHARYNGITIS	SORE THROAT	77	3	23	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	77	1	40	Mild	No	Recovered	None	Yes
			Body	BACK PAIN	BACKACHE	77	5	6	Mild	No	Recovered	None	No
				NECK PAIN	NECKPAIN	77	7	13	Mild	No	Recovered	None	No
			Skin	HERPES SIMPLEX DERM	COLD SORE	77	17	24	Mild	No	Recovered	None	No
			Urogenital	INFECTION URINARY TRACT	BLADDER INFECTION	77	22	22	Mild	No	Recovered	None	No
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	77	28	34	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151099	52/Female	Placebo	Special Senses	TASTE PERVERSION	TASTE DISTURBANCE OF SENSATION	77	51	61	Mild	No	Recovered	None	Yes
			Digestive	VOMITING	VOMITING	77	44	44	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	77	44	44	Mild	No	Recovered	None	Yes
			Body	CHILLS	CHILLS	77	44	44	Mild	No	Recovered	None	Yes
151100	42/Female	RBX	Digestive	DYSPEPSIA	HEARTBURN	36		34	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	DROWSINESS	36	-75	1	Mild	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRED VISION	36		34	Mild	No	Recovered	None	Yes
			Cardiovascular	TACHYCARDIA	RAPID HEART RATE	36		7	Mild	No	Recovered	None	No
			Body	LOCALIZED PAIN	RIB PAIN	36	5		Mild	No	Not recovered	None	No
				UPPER RESPIRATORY INFECTION	COLD	36	0	8	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHES	36	7		Mild	No	Not recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	36	34		Severe	No	Not recovered	Drug permanen-tly withdrawn	Yes
151117	49/Female	RBX	Nervous	RESTLESSNESS	RESTLESSNESS	56	0	4	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151117	49/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	56	0		Mild	No	Not recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	56	0	2	Mild	No	Recovered	None	Yes
			Hemic and Lymphatic	ECCHYMOSIS/BRUISE	BRUISED HIP	56	3	4	Mild	No	Recovered	None	No
			Body	LOCALIZED PAIN	KNEE PAIN	56	10	10	Mild	No	Recovered	None	No
151118	47/Male	RBX	Digestive	CONSTIPATION	CONSTIPATION	55	-86	28	Mild	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	55	-86	28	Mild	No	Recovered	None	Yes
				EJACULATION ABNORM-AL	DELAYED EJACULATI-ON	55	-86	28	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	55	-86	28	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	55	9	10	Mild	No	Recovered	None	Yes
151153	44/Male	RBX	Digestive	TOOTHACHE	TOOTH PAIN	20	-6	14	Mild	No	Recovered	None	No
			Nervous	TREMOR	TREMBLING	20	1	3	Mild	No	Recovered	None	Yes
				DIZZINESS	DIZZINESS	20	1	1	Mild	No	Recovered	None	Yes
			Cardiovascular	PALPITATION	HEART PALPITATIONS	20	1	1	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	20	6	11	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
151153	44/Male	RBX	Digestive	NAUSEA	NAUSEA	20	2	3	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	LETHARGY	20	2	14	Mild	No	Recovered	None	Yes
				INSOMNIA	INSOMNIA	20	1	14	Mild	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	20	1	14	Mild	No	Recovered	None	Yes
				PAIN TESTICULAR	TESTICLE PAIN	20	3	21	Mild	No	Recovered	None	Yes
				IMPOTENCE	ERECTILE DYSFUNCT-ION	20	0	16	Mild	No	Recovered	None	Yes
				EJACULATION ABNORM-AL	DELAYED EJACULATI-ON	20	3		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Digestive	DRY MOUTH	DRY MOUTH	20	14		Mild	No	Not recovered	None	Yes
171015	45/Female	Placebo	Digestive	DRY MOUTH	DRY MOUTH	85	4		Mild	No	Not recovered	None	Yes
			Special Senses	EYE PAIN	BURNING EYES	85	8		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	85	14	14	Severe	No	Recovered	None	No
			Cardiovascular	SINUS TACHYCARDIA	SINUS TACHYCARDIA	85	28	28	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	85	29	29	Moderate	No	Recovered	None	No
				TRAUMA	BEE STING	85	32	32	Moderate	No	Recovered	None	No

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
171015	45/Female	Placebo	Body	BACK PAIN	BACK ACHE	85	60	61	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	85	-29		Mild	No	Not recovered	None	No
			Body	HEADACHE	HEADACHE	85	-10	-10	Mild	No	Recovered	None	No
				NECK RIGID	STIFF NECK	85	84		Mild	No	Not recovered	None	No
				LOCALIZED PAIN	SORE SHOULDER	85	76	76	Mild	No	Recovered	None	No
171016	37/Male	RBX	Urogenital	RETENTION URINARY	URINARY RETENTION		2	36	Severe	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH		0	14	Moderate	No	Recovered	None	Yes
				CONSTIPATION	CONSTIPATION		3		Moderate	No	Unknown	None	Yes
			Nervous	INSOMNIA	INSOMNIA		20	22	Mild	No	Recovered	None	No
			Body	TRAUMA	LACERATION TO LEG		27	27	Mild	No	Recovered	None	No
				BACK PAIN	BACK ACHE		36	36	Mild	No	Recovered	None	No
			Cardiovascular	MIGRAINE	HEADACHE-MIGRAINE		40	40	Mild	No	Recovered	None	No
			Body	ENVIRONMENTAL ALLERGY	SEASONAL ALLERGIES		46		Mild	No	Unknown	None	No
				LOCALIZED PAIN	GENITAL PAIN		14	16	Mild	No	Recovered	None	No

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

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171016	37/Male	RBX	Metabolic and Nutritional	BILIRUBINEMIA	ABNORMAL BILIRUBIN - INCREASE		29		Mild	No	Unknown	None	Yes
171027	52/Female	RBX	Body	CHILLS	CHILLS	35	0	6	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	35	11	12	Mild	No	Recovered	None	No
							16	17	Mild	No	Recovered	None	No
							26	27	Moderate	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	URINARY HESITANCY	35	10	11	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	35	28		Moderate	No	Not recovered	None	Yes
				MANIC SYMPTOMS	RACING THOUGHTS	35	12		Moderate	No	Not recovered	None	Yes
				ANXIETY	STRESS	35	33	34	Moderate	No	Recovered	None	No
			Body	FATIGUE	FATIGUE	35	23		Mild	No	Not recovered	None	No
				GENERALIZED PAIN	BODY ACHES	35	21		Mild	No	Not recovered	None	No
				INFECTION FUNGAL NOS	YEAST INFECTION	35	9	12	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	35	20	25	Mild	No	Recovered	None	Yes
			Skin	DISORDER HAIR	PILOERECTION	35	1	6	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

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171027	52/Female	RBX	Body	GENERALIZED PAIN	BODY ACHES	35	16	17	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	35	11	11	Mild	No	Recovered	None	No
171028	45/Female	RBX	Nervous	INSOMNIA	INSOMNIA	24	10	12	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	24	1	4	Mild	No	Recovered	None	Yes
			Nervous	CONCENTRATION IMPAIRED	IMPAIRED CONCENTR-ATION	24	1	4	Moderate	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	24	17	19	Mild	No	Recovered	None	Yes
				DYSPEPSIA	HEART BURN	24	18	21	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	24	17	18	Mild	No	Recovered	None	Yes
				ANXIETY	JITTERY	24	1	12	Moderate	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	24	6	11	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	LIGHT HEADED	24	17		Mild	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	24	1	4	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	24	1	12	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	24	17	19	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
171061	47/Female	RBX	Body	FATIGUE	FATIGUE	35	3	5	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	35	15	17	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	35	16	17	Severe	No	Recovered	None	No
			Nervous	NERVOUSNESS	FEELING EDGY	35	18	20	Mild	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	35	15	17	Mild	No	Recovered	None	Yes
				DRY MOUTH	DRY MOUTH	35	1		Mild	No	Not recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	35	1		Mild	No	Not recovered	None	No
			Digestive	NAUSEA	NAUSEA	35	21	22	Mild	No	Recovered	None	No
			Nervous	MANIC SYMPTOMS	HYPOMANIA	35	27		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Metabolic and Nutritional	PERIPHERAL EDEMA	FEET SWELLING	35	27		Mild	No	Not recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	35	26		Mild	No	Not recovered	None	Yes
			Respiratory	RHINITIS	POST NASAL DRIP	35	20		Moderate	No	Not recovered	None	No
			Body	HEADACHE	HEADACHE	35	10	10	Severe	No	Recovered	None	No
			Respiratory	RHINITIS	VASOMOTOR RHINITIS	35	24		Mild	No	Not recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
171062	52/Female	Placebo	Nervous	HYPERTONIA	MUSLE SPASM IN BACK	64	6	17	Mild	No	Recovered	None	No
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	64	0	3	Mild	No	Recovered	None	Yes
				DYSPEPSIA	HEART BURN	64	0	6	Mild	No	Recovered	None	No
			Cardiovascular	TACHYCARDIA	TACHYCARDIA	64	0	1	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	SEDATION	64	0	4	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	64	0		Mild	No	Not recovered	None	Yes
			Body	BACK PAIN	BACK ACHE	64	7	7	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	64	-72	40	Moderate	No	Recovered	None	No
				NIGHTMARES	NIGHTMARES	64	11	30	Mild	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	INDIGESTION	64	44	48	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHES	64	9	10	Mild	No	Recovered	None	Yes
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	64	2	50	Mild	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	INDIGESTION	64	44	48	Moderate	No	Recovered	Dose increased	No
			Body	HEADACHE	HEADACHE	64	9	10	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
171062	52/Female	Placebo	Body	UPPER RESPIRATORY INFECTION	VIRAL UPPER RESPIRATORY INFECTION	64	51	61	Moderate	No	Recovered	None	No
171063	27/Male	Placebo	Body	ASTHENIA	FEELING TIRED	88	-869	11	Moderate	No	Recovered	None	No
			Nervous	LIBIDO DECREASED	LOSS OF SEX DRIVE	88	-869	61	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	88	0	19	Mild	No	Recovered	None	Yes
			Nervous	ANXIETY	FEELING WIRED	88	0	38	Mild	No	Recovered	None	Yes
				INSOMNIA	INSOMNIA	88	0	11	Moderate	No	Recovered	None	Yes
			Skin	DIAPHORETIC	COLD SWEATS	88	1	11	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	88	11	38	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	88	27	27	Moderate	No	Recovered	None	No
			Cardiovascular	VASODILATION	FLUSHING	88	46	47	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	88	79	79	Moderate	No	Recovered	None	No
				LOCALIZED PAIN	SHOULDER PAIN	88	85	86	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHE	88	63	63	Mild	No	Recovered	None	No
				LOCALIZED PAIN	SHOULDER PAIN	88	79	80	Mild	No	Recovered	None	No

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Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
171064	21/Female	RBX	Nervous	INSOMNIA	INSOMNIA	8	4	11	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	8	1	10	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	8	4	11	Mild	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	8	1	8	Mild	No	Recovered	None	No
				TRAUMA	MOTOR VEHICLE ACCIDENT	8	8	8	Mild	No	Recovered	None	No
					LACERATION TO RIGHT KNEE	8	8	22	Moderate	No	Recovered	None	No
				HANGOVER	HANGOVER	8	1	3	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHE	8	1	4	Mild	No	Recovered	None	No
181083	58/Male	RBX	Digestive	LOOSE STOOLS NEC	VERY LOOSE BOWEL MOVEMENT	143	-5	-1	Moderate	No	Recovered	None	No
			Nervous	INSOMNIA	SLEEP DIFFICULTY	143	1		Mild	No	Not recovered	None	Yes
			Urogenital	DYSURIA	SLIGHT URINARY ITCHING SENSATION	143	1		Mild	No	Not recovered	None	Yes
			Nervous	PARESTHESIA	TINGLING IN UPPER SPINE	143	1	37	Mild	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
181083	58/Male	RBX	Urogenital	URINATION IMPAIRED	URINARY HESITANCY	143	1	37	Mild	No	Recovered	None	Yes
				NOCTURIA	URINARY FREQUENCY AT NIGHT	143	1		Mild	No	Not recovered	None	Yes
			Digestive	DIARRHEA	DIARRHEA	143	44	45	Mild	No	Recovered	None	No
			Body	ALLERGIC REACTION	UPPER RESPIRATORY ALLERGIC RESPONSE	143	46	47	Mild	No	Recovered	None	No
				FLU SYNDROME	FLU SYMPTOMS SORE THROAT, ACHES. COUGH	143	53	73	Mild	No	Recovered	None	No
			Digestive	DIARRHEA	DIARRHEA	143	91	91	Mild	No	Recovered	None	No
			Body	ENVIRONMENTAL ALLERGY	SEASONAL ALLERGY SYMPTOMS	143	110		Mild	No	Not recovered	None	No
			Respiratory	RHINITIS	POST NASAL DRIP	143	74	104	Mild	No	Recovered	None	No
			Special Senses	TINNITUS	TINNITUS CHANGED TONE-"HIGH FREQUE-NCY TO LOW RUMBLE"	143	14		Mild	No	Not recovered	None	Yes
					DIMINISHED OCCURR-ENCE OF TINNITUS FROM BASELINE	143	107		Mild	No	Not recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
181083	58/Male	RBX	Nervous	LIBIDO DECREASED	DIMINISHED LIBIDO	143	90		Mild	No	Not recovered	None	Yes
			Urogenital	IMPOTENCE	ERECTILE DIFFICULTY-OBTAINING, MAINTAINING	143	119		Mild	No	Not recovered	None	Yes
181084	32/Male	Placebo	Digestive	DYSPEPSIA	HEARTBURN	120	-2	-1	Mild	No	Recovered	None	No
			Respiratory	SINUSITIS	SINUS PRESSURE	120	-3	23	Mild	No	Recovered	None	No
			Skin	DIAPHORETIC	SWEATING	120	1	9	Moderate	No	Recovered	None	Yes
			Body	ALLERGIC REACTION	ALLERGIC RESPIRATORY SYMPTOMS	120	9	39	Moderate	No	Recovered	None	No
			Urogenital	URINATION IMPAIRED	SLOWED URINARY STREAM	120	1	46	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	INCREASE SWEAT WITH EXERTION	120	10	23	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	120	24	50	Mild	No	Recovered	Dose increased	Yes
			Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	120	21	35	Mild	No	Recovered with sequelae	Dose increased	Yes
			Body	UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	120	28	44	Mild	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

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181084	32/Male	Placebo	Body	HEADACHE	SINUS PRESSURE HEADACHE	120	35	36	Mild	No	Recovered	None	No
			Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD HANDS	120	3	64	Moderate	No	Recovered	Dose reduced	Yes
			Nervous	INSOMNIA	INSOMNIA	120	32	51	Moderate	No	Recovered	Dose reduced	Yes
			Musculo-Skeletal	MYALGIA	MYALGIA, HANDS	120	67	81	Mild	No	Recovered	None	No
			Body	BACK PAIN	LOWER BACK PAIN	120	72	81	Mild	No	Recovered	None	No
			Musculo-Skeletal	MYALGIA	MUSCULAR PAINS	120	93	97	Moderate	No	Recovered	None	No
			Respiratory	SINUSITIS	SINUS PAIN	120	-3	23	Mild	No	Recovered	None	No
			Cardiovascular	DISORDER PERIPHERAL VASCULAR	COLD FEET	120	3	64	Moderate	No	Recovered	Dose reduced	Yes
			Musculo-Skeletal	MYALGIA	MYALGIA, ARMS	120	67	81	Mild	No	Recovered	None	No
181105	37/Female	RBX	Nervous	NIGHTMARES	NIGHTMARES	56	-7	-1	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING	56	2	20	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	56	3	8	Moderate	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	56	15	31	Moderate	No	Recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
181105	37/Female	RBX	Body	LOCALIZED EDEMA	SWOLLEN HEEL	56	23	32	Moderate	No	Recovered	None	No
			Urogenital	DISORDER MENSTRUAL NEC	MENSTRUAL CHANGES	56	9		Mild	No	Not recovered	None	Yes
			Nervous	NERVOUSNESS	INCREASE IRRITABI-LITY	56	23	29	Moderate	No	Recovered	None	Yes
				DEPRESSIVE SYMPTOMS	INCREASED SEVERITY DEPRESSED MOOD	56	26	29	Moderate	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	INDIGESTION	56	36	36	Mild	No	Recovered	None	No
181106	28/Male	RBX	Skin	DIAPHORETIC	COLD SWEATS	15	0		Severe	No	Not recovered	None	Yes
			Urogenital	DYSURIA	URINARY PRESSURE	15	2		Moderate	No	Not recovered	None	Yes
				EJACULATION ABNORM-	SPONTANEOUS	15	3	3	Mild	No	Recovered	None	Yes
				AL	EJACULATORY DISCHARGE		9		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Special Senses	TASTE PERVERSION	METALLIC TASTE	15	0		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
181135	31/Female	RBX	Skin	DIAPHORETIC	INCREASED SWEATING	37	3	5	Mild	No	Recovered	None	Yes
			Nervous	AGITATION	EPISODIC AGITATION	37	4	8	Moderate	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
181135	31/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	37	2	26	Mild	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	BLURRED VISION	37	10	10	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	LIGHTHEADED	37	12	12	Mild	No	Recovered	None	Yes
			Skin	DISORDER SKIN NEC	SKIN ABNORMALITIES	37	10	50	Moderate	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	HEARTBURN	37	10	41	Moderate	No	Recovered	None	Yes
			Body	UPPER RESPIRATORY INFECTION	UPPER RESPIRATORY INFECTION	37	21	26	Moderate	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING EXERCISE	37	15	38	Moderate	No	Recovered	None	Yes
			Nervous	NERVOUSNESS	IRRITABILITY	37	18	50	Severe	No	Recovered	None	Yes
181136	55/Female	RBX	Nervous	INSOMNIA	RESTLESS SLEEP	57	1	3	Mild	No	Recovered	None	Yes
							8		Moderate	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	57	14	14	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	57	26		Moderate	No	Not recovered	Dose increased	Yes
191013	36/Female	RBX	Body	HEADACHE	HEADACHE	44	-2	-2	Moderate	No	Recovered	None	No
			Nervous	NERVOUSNESS	IRRITABILITY	44	8	12	Moderate	No	Recovered	None	No

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Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
191013	36/Female	RBX	Respiratory	COUGH	COUGH	44	6	9	Mild	No	Recovered	None	No
			Musculo-Skeletal	MYALGIA	MYALGIAS	44	6	9	Mild	No	Recovered	None	No
			Body	FEVER	FEVER (100 DEGREE-S)	44	6	6	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	44	3	5	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	44	2	12	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	44	1	7	Mild	No	Recovered	None	Yes
				CONSTIPATION	CONSTIPATION	44	1	2	Mild	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING	44	36	37	Mild	No	Recovered	None	Yes
			Body	CHEST PAIN	CHEST HEAVINESS	44	34	35	Mild	No	Recovered	None	No
			Digestive	FLATULENCE	FLATULENCE	44	34	34	Mild	No	Recovered	None	No
			Nervous	AMNESIA	DECREASED MEMORY	44	23	32	Mild	No	Recovered	None	No
				HYPESTHESIA	(R) SIDE OF BODY NUMBNESS	44	21	22	Moderate	No	Recovered	None	No
			Digestive	APPETITE INCREASED	INCREASED APPETITE	44	2	5	Mild	No	Recovered	None	No
			Special Senses	TINNITUS	TINNITUS (R) EAR	44	40	40	Mild	No	Recovered	None	Yes

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Adverse Events - Listing by Patient
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191013	36/Female	RBX	Respiratory	EPISTAXIS	NOSE BLEED	44	40	40	Mild	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	44	42		Mild	No	Unknown	None	No
			Body	HEADACHE	HEADACHE (POST-OCCIPITAL)	44	41	43	Mild	No	Recovered	None	Yes
				BACK PAIN	LOWER BACK PAIN	44	41	43	Mild	No	Recovered	None	No
			Digestive	LOOSE STOOLS NEC	LOOSE STOOL	44	41	42	Mild	No	Recovered	None	No
			Musculo-Skeletal	CRAMP LEGS	BILATERAL LEG CRAMPS	44	34	37	Mild	No	Recovered	None	No
			Skin	DIAPHORETIC	INCREASED SWEATING	44	40		Mild	No	Not recovered	None	Yes
			Body	CHEST PAIN	CHEST HEAVINESS	44	23	28	Mild	No	Recovered	None	No
			Nervous	AMNESIA	DECREASED MEMORY	44	16	16	Mild	No	Recovered	None	No
			Body	BACK PAIN	LOWER BACK PAIN	44	23	28	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	44	8	9	Mild	No	Recovered	None	No
							11	13	Mild	No	Recovered	None	No
							16	35	Mild	No	Recovered	None	No
							38	38	Mild	No	Recovered	None	No

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191013	36/Female	RBX	Nervous	DIZZINESS	DIZZINESS	44	16	20	Mild	No	Recovered	None	Yes
							36	37	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	44	13	13	Mild	No	Recovered	None	Yes
							34	41	Mild	No	Recovered	None	Yes
			Body	NECK PAIN	NECK ACHE	44	8	9	Mild	No	Recovered	None	Yes
							13	13	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	44	12	12	Mild	No	Recovered	None	No
							40	40	Mild	No	Recovered	None	No
			Musculo-Skeletal	CRAMP LEGS	BILATERAL LEG CRAMPS	44	23	28	Mild	No	Recovered	None	No
			Nervous	HYPESTHESIA	NUMBNESS (R) SIDE OF BODY	44	21	22	Mild	No	Recovered	None	No
			Body	ABDOMINAL CRAMP	STOMACH CRAMP	44	6	6	Mild	No	Recovered	None	No
				NECK PAIN	NECK ACHE	44	36	37	Mild	No	Recovered	None	No
				REACTION UNEVALUAB-	LIMB HEAVINESS	44	16	21	Mild	No	Recovered	None	No
				LE			29	32	Mild	No	Recovered	None	No

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191013	36/Female	RBX	Body	REACTION UNEVALUAB- LE	LIMB HEAVINESS	44	38	40	Mild	No	Recovered	None	No
					HEAVINESS IN RIGHT SIDE OF BODY	44	23	28	Mild	No	Recovered	None	No
					LEGS HEAVY	44	36	37	Mild	No	Recovered	None	No
			Nervous	MUSCLE CRAMP	BILATERAL CRAMPS IN FEET	44	23	28	Mild	No	Recovered	None	No
			Body	FATIGUE	FATIGUE	44	34	37	Mild	No	Recovered	None	No
191014	47/Male	RBX	Digestive	DRY MOUTH	DRY MOUTH	156	0	32	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	156	0	16	Mild	No	Recovered	None	Yes
			Body	CHILLS	COLD FLASHES	156	0	16	Mild	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	DECREASED FORCE OF URINARY STREAM	156	1	30	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	156	0	15	Moderate	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	156	2	44	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	INCREASED SWEATING	156	0	46	Moderate	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	156	5	6	Mild	No	Recovered	None	Yes

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191014	47/Male	RBX	Nervous	PARESTHESIA	INTERMITTENT TINGLING OF ARMS	156	0	7	Mild	No	Recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	156	9	11	Moderate	No	Recovered	None	Yes
				TOOTH ABSCESS	TOOTH ABCESS	156	16	27	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	156	34	34	Mild	No	Recovered	None	Yes
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	156	22		Mild	No	Not recovered	None	Yes
			Digestive	TOOTHACHE	TOOTHACHE	156	36	44	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	156	68	68	Mild	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	156	72	124	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	156	85	85	Mild	No	Recovered	None	No
			Nervous	PARESTHESIA	TINGLING SCALP	156	89	89	Mild	No	Recovered	None	No
			Urogenital	EJACULATION ABNORM-AL	PREMATURE EJACULA-TION	156	89		Mild	No	Unknown	None	No
			Nervous	NEOPLASM CNS	BRAIN TUMOR	156	159		Severe	Yes	Unknown	Drug permanen-tly withdrawn	No
201067	31/Male	RBX	Nervous	LIBIDO DECREASED	DECREASE IN LIBIDO	120	3	85	Mild	No	Recovered	None	Yes

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201067	31/Male	RBX	Nervous	PARESTHESIA	TINGLING IN ARMS	120	1	86	Moderate	No	Recovered	None	Yes
					TINGLING IN LEGS	120	1	86	Moderate	No	Recovered	None	Yes
			Urogenital	URINATION IMPAIRED	DIMINISHED FLOW OF URINE	120	1	15	Mild	No	Recovered	None	Yes
				EJACULATION ABNORM-AL	DELAYED EJACULATI-ON	120	2	16	Mild	No	Recovered	None	Yes
			Nervous	PARESTHESIA	TINGLING IN HEAD	120	1	86	Moderate	No	Recovered	None	Yes
			Urogenital	IMPOTENCE	UNABLE TO REACH FULL ERECTION	120	3	24	Mild	No	Recovered	None	Yes
			Body	CHEST PAIN	CHEST PAIN	120	5	6	Mild	No	Recovered	None	Yes
			Nervous	RESTLESSNESS	RESTLESSNESS	120	0	2	Mild	No	Recovered	None	Yes
			Body	CHEST PAIN	CHEST PAIN	120	11	12	Mild	No	Recovered	None	Yes
			Urogenital	RETENTION URINARY	SENSATION OF URINARY RETENTION	120	1	15	Mild	No	Recovered	None	Yes
			Respiratory	DYSPNEA	SHORTNESS OF BREATH	120	11	12	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS WHEN STANDING UP	120	36	99	Mild	No	Recovered	None	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
201067	31/Male	RBX	Nervous	DIZZINESS	LIGHT HEADEDNESS WHEN STANDING UP	120	36	99	Mild	No	Recovered	None	Yes
			Body	CHILLS	COLD SENSATION WHILE EXERCISING	120	39	97	Mild	No	Recovered	None	Yes
					COLD SENSATIONS THROUGHOUT DAY	120	48	48	Moderate	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HEAT SENSATIONS	120	55	56	Mild	No	Recovered	None	Yes
			Body	LOCALIZED PAIN	PAIN IN RIGHT GROIN AREA	120	67	80	Mild	No	Recovered	None	No
			Cardiovascular	VASODILATION	HEAT FLASHES	120	56	72	Moderate	No	Recovered	None	Yes
			Respiratory	PHARYNGITIS	SORE THROAT	120	19	21	Mild	No	Recovered	None	No
			Nervous	RESTLESSNESS	RESTLESSNESS	120	82	100	Mild	No	Recovered	None	Yes
201068	37/Female	Placebo	Digestive	LIVER FUNCTION TESTS ABNORMAL NOS	ELEVATED LIVER ENZYMES	94	-11	77	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	94	6	17	Mild	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	94	1	65	Mild	No	Recovered	None	Yes
			Nervous	PARESTHESIA	HEAD TINGLING	94	1	17	Mild	No	Recovered	None	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
201068	37/Female	Placebo	Body	ASTHENIA	TIREDNESS	94	1	3	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	LIGHT HEADEDNESS	94	3	5	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	94	3	63	Mild	No	Recovered	None	Yes
			Respiratory	RHINITIS	DRY NASAL PASSAGES	94	3	63	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	94	2	78	Mild	No	Recovered	None	Yes
			Nervous	SOMNOLENCE	SLEEPINESS	94	1	3	Mild	No	Recovered	None	Yes
				PARESTHESIA	HEAD TINGLING	94	24	63	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	94	24	42	Mild	No	Recovered	None	Yes
			Urogenital	OLIGURIA	DECREASED FREQUENCY OF URINATION	94	21	63	Mild	No	Recovered	None	Yes
			Digestive	HEMORRHOID	HEMORROIDS	94	15	78	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	SLEEPLESSNESS	94	59	64	Mild	No	Recovered	None	Yes
				DIZZINESS	LIGHT HEADEDNESS	94	61	65	Mild	No	Recovered	None	Yes
201091	34/Female	RBX	Nervous	LIBIDO DECREASED	DECREASED LIBIDO	8			Moderate	No	Not recovered	None	No
			Body	TRAUMA	MUSCLE STRAIN UNDER LEFT BREAST	8	-7		Severe	No	Not recovered	None	No

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
201091	34/Female	RBX	Nervous	PARESTHESIA	HEAD TINGLING	8	0	6	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	8	0		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	8	3	6	Mild	No	Recovered	None	Yes
				ASTHENIA	TIREDNESS	8	3		Mild	No	Not recovered	None	Yes
201092	41/Female	RBX	Nervous	INSOMNIA	INSOMNIA	24	-41	31	Moderate	No	Recovered	None	No
			Body	HEADACHE	INTERMITTENT HEADACHE	24	1	38	Severe	No	Recovered	None	Yes
				BACK PAIN	BACKACHE	24	2	8	Mild	No	Recovered	None	No
				ASTHENIA	TIREDNESS	24	3	36	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	24	2		Mild	No	Not recovered	None	Yes
			Nervous	SUICIDAL TENDENCY	SUICIDAL DEPRESSI-ON	24	22	33	Severe	Yes	Recovered	Drug permanen-tly withdrawn	No
				INSOMNIA	SLEEPLESSNESS	24	-41	31	Mild	No	Recovered	None	No
201123	43/Female	RBX	Body	ASTHENIA	TIREDNESS	56	-28		Mild	No	Not recovered	None	No
				UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	56	0	2	Mild	No	Recovered	None	No

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201123	43/Female	RBX	Nervous	DIZZINESS	DIZZINESS	56	3	3	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	56	9		Mild	No	Not recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS	56	11		Mild	No	Not recovered	None	Yes
			Urogenital	DISORDER VULVOVAGI-NAL	VAGINAL DRYNESS	56	8		Mild	No	Not recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	56	14		Mild	No	Not recovered	None	Yes
211039	53/Female	RBX	Nervous	INSOMNIA	WORSE INSOMNIA	60	1		Moderate	No	Not recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	60	2	34	Moderate	No	Recovered	None	Yes
				DYSPEPSIA	HEARTBURN	60	29	44	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	60	15	16	Moderate	No	Recovered	None	Yes
					SINUS HEADACHE	60	18	18	Moderate	No	Recovered	None	No
211040	53/Female	RBX	Respiratory	PHARYNGITIS	SORE THROAT	79	14	17	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	BRIEF DIZZINESS	79	23	49	Mild	No	Recovered	None	Yes
			Body	FLU SYNDROME	FLU	79	14	17	Mild	No	Recovered	None	No
			Cardiovascular	HYPERTENSION	ELEVATED BLOOD PRESSURE	79	-11		Mild	No	Not recovered	None	No

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211040	53/Female	RBX	Metabolic and Nutritional	PERIPHERAL EDEMA	BILATERAL HAND EDEMA	79	35		Mild	No	Not recovered	None	No
			Nervous	CHANGE IN DREAMS	STRANGE DREAMS	79	59		Mild	No	Not recovered	None	Yes
				PARESTHESIA	TINGLING IN RT. ARM	79	62		Mild	No	Not recovered	None	No
211109	43/Male	RBX	Cardiovascular	PALPITATION	PALPITATIONS	78	2	31	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	NIGHT SWEATS	78	2	56	Mild	No	Recovered	None	Yes
			Cardiovascular	HYPOTENSION POSTUR-AL	OCCASIONAL SYMPTO-MS OF ORTHOSTATIC HYPOTENSION/ DIZZINESS ON STANDING	78	4	36	Mild	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	INDIGESTION	78	0		Moderate	No	Not recovered	None	Yes
				DRY MOUTH	DRY MOUTH	78	0	72	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	78	62	72	Moderate	No	Recovered	None	Yes
211110	54/Female	Placebo	Nervous	DIZZINESS	LIGHT HEADEDNESS	78	0	4	Severe	No	Recovered	Dose reduced	Yes
				SOMNOLENCE	SEDATION	78	0	4	Severe	No	Recovered	Dose reduced	Yes
			Digestive	NAUSEA	NAUSEA	78	0	4	Severe	No	Recovered	Dose reduced	Yes

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211110	54/Female	Placebo	Digestive	APPETITE DECREASED	DECREASED APPETITE	78	0	8	Mild	No	Recovered	None	Yes
			Skin	DIAPHORETIC	NIGHT SWEATS	78	0	59	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	78	3	4	Moderate	No	Recovered	None	Yes
			Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	78	8	18	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	LIGHT HEADEDNESS	78	16	16	Mild	No	Recovered	None	Yes
			Body	GENERALIZED EDEMA	FLUID RETENTION	78	27	34	Mild	No	Recovered	None	No
			Respiratory	RHINITIS	RHINITIS	78	21	25	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	78	29	32	Mild	No	Recovered	None	Yes
			Respiratory	RHINITIS	RHINITIS	78	30	32	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	78	44	64	Mild	No	Recovered	None	Yes
			Metabolic and Nutritional	WEIGHT INCREASE	WEIGHT GAIN	78	53	70	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	78	66	66	Moderate	No	Recovered	None	No
			Digestive	NAUSEA	AM NAUSEA	78	29	29	Mild	No	Recovered	None	Yes
211145	41/Male	RBX	Digestive	DRY MOUTH	DRY MOUTH	46	1		Mild	No	Not recovered	None	Yes

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Adverse Events - Listing by Patient
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211145	41/Male	RBX	Nervous	INSOMNIA	INSOMNIA	46	1		Moderate	No	Not recovered	None	Yes
				SOMNOLENCE	DAYTIME SLEEPINESS	46	1		Moderate	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	INCREASED SWEATING	46	1		Mild	No	Not recovered	None	Yes
			Respiratory	RHINITIS	RHINITIS	46	9	20	Mild	No	Recovered	None	No
			Cardiovascular	PALPITATION	HEART RACING	46	1	8	Mild	No	Recovered	None	Yes
			Digestive	DYSPEPSIA	HEARTBURN	46	1	8	Moderate	No	Recovered	None	Yes
			Nervous	LIBIDO DECREASED	DECREASED LIBIDO	46	1		Moderate	No	Not recovered	None	Yes
			Urogenital	SEXUAL FUNCTION ABNORMAL	SEXUAL DYSFUNCTION	46	9		Moderate	No	Not recovered	None	Yes
211146	57/Male	RBX	Special Senses	TINNITUS	TINNITUS	57	-57	11	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	WORSE INSOMNIA	57	1	3	Mild	No	Recovered	None	Yes
			Body	CHILLS	CHILLS	57	1		Mild	No	Not recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	57	1		Moderate	No	Not recovered	None	Yes
			Urogenital	URINATION IMPAIRED	DIFFICULTY URINAT-ING	57	2	11	Mild	No	Recovered	None	Yes
			Respiratory	RHINITIS	RHINITIS	57	8	9	Mild	No	Recovered	None	No

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Adverse Events - Listing by Patient
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211146	57/Male	RBX	Urogenital	EJACULATION ABNORM-AL	PREMATURE EJACULA-TION	57	16	47	Mild	No	Recovered	None	Yes
			Respiratory	RHINITIS	RHINITIS	57	30	34	Mild	No	Recovered	None	No
			Urogenital	IMPOTENCE	IMPOTENCE	57	36		Moderate	No	Not recovered	None	Yes
			Respiratory	RHINITIS	RHINITIS	57	45	55	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	57	55	55	Mild	No	Recovered	None	No
			Metabolic and Nutritional	HYPERCHOLESTEREMIA	HYPERCHOLESTROLEM-IA	57	52		Mild	No	Not recovered	None	No
			Body	HEADACHE	HEADACHE	57	0	0	Mild	No	Recovered	None	No
211147	37/Female	RBX	Nervous	DIZZINESS	LIGHTHEADED	8	3		Mild	No	Not recovered	None	Yes
				ANXIETY	ANXIETY ATTACK	8	1	1	Moderate	No	Recovered	None	Yes
				INSOMNIA	INSOMNIA	8	2	3	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	8	2		Mild	No	Not recovered	None	Yes
				SUICIDE ATTEMPT	SUICIDE ATTEMPT	8	7	14	Severe	Yes	Recovered	Drug permanen-tly withdrawn	Yes
221033	44/Male	RBX	Nervous	ANXIETY	JITTERINESS	141	1	5	Mild	No	Recovered	None	Yes

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
221033	44/Male	RBX	Body	ASTHENIA	WEAKNESS	141	63	64	Moderate	No	Recovered	None	Yes
			Special Senses	BLURRED VISION	FOCUSING DIFFICULTY	141	63	64	Moderate	No	Recovered	None	Yes
221034	40/Female	RBX	Body	HEADACHE	HEADACHE	42	-5	-4	Moderate	No	Recovered	None	No
				FATIGUE	FATIGUE	42	-7		Moderate	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	NIGHT SWEATS	42	0	31	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	42	15	16	Mild	No	Recovered	None	Yes
							21	22	Moderate	No	Recovered	None	Yes
							24	24	Moderate	No	Recovered	None	Yes
							28	29	Moderate	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	42	38	38	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	42	36	36	Moderate	No	Recovered	None	Yes
							40	40	Moderate	No	Recovered	None	Yes
221129	51/Male	RBX	Urogenital	URINATION IMPAIRED	URINARY HESITANCY	6	1		Moderate	No	Not recovered	Drug permanently withdrawn	Yes

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221129	51/Male	RBX	Urogenital	IMPOTENCE	IMPOTENCE	6	1		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	6	1		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Skin	DIAPHORETIC	EXCESSIVE PERSPIR-ATION	6	1		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Nervous	AGITATION	AGITATION	6	1		Mild	No	Not recovered	Drug permanen-tly withdrawn	Yes
				INSOMNIA	INSOMNIA	6	1		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
221130	51/Female	RBX	Cardiovascular	VASODILATION	HOT FLASHES		2		Moderate	No	Unknown	None	Yes
			Nervous	INSOMNIA	INSOMNIA		8	25	Mild	No	Recovered	None	Yes
231001	50/Female	RBX	Nervous	INSOMNIA	INSOMNIA	128	0		Severe	No	Not recovered	None	Yes
			Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	128	9		Mild	No	Not recovered	None	Yes
			Urogenital	RETENTION URINARY	URINE RETENTION	128			Moderate	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	128	9		Mild	No	Not recovered	None	Yes
				DISORDER TONGUE	BUMPS ON UNDER SIDE OF TONGUE	128	15	22	Mild	No	Recovered	None	No

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231001	50/Female	RBX	Skin	SKIN EROSION NEC	FACIAL EXCORIATION	128	15	115	Mild	No	Recovered	None	No
			Digestive	DISORDER TONGUE	BOILS ON TOP BACK OF TONGUE	128	23		Mild	No	Not recovered	None	No
			Body	UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	128	42	45	Mild	No	Recovered	None	No
				REACTION UNEVALUAB-LE	COSMETIC SURGERY LIPOSECTION ON STOMACH	128	52	52	Mild	No	Recovered	None	No
				HEADACHE	HEADACHE	128	71	71	Moderate	No	Recovered	None	No
				CHEST PAIN	CHEST PAIN	128	97	107	Mild	No	Recovered	Drug permanen-tly withdrawn	No
			Nervous	NERVOUSNESS	INCREASED NERVOUS-NESS	128	109	112	Mild	No	Recovered	None	No
			Cardiovascular	HYPERTENSION	ELEVATED BLOOD PRESSURE	128	70		Mild	No	Not recovered	None	No
231002	40/Female	RBX	Body	FATIGUE	FATIGUE	28			Moderate	No	Not recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	28	0	10	Severe	No	Recovered	None	Yes
				SCIATICA NOS	SCIATIC NERVE IRRITATION	28	11		Severe	No	Not recovered	None	No

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231002	40/Female	RBX	Nervous	INSOMNIA	INSOMNIA	28	12		Severe	No	Not recovered	None	No
231079	65/Male	RBX	Digestive	DRY MOUTH	DRY MOUTH	136	2	39	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	136	2	43	Mild	No	Recovered	None	Yes
			Urogenital	RETENTION URINARY	URINE RETENTION	136	0	42	Moderate	No	Recovered	None	Yes
							53	56	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	136	53	56	Mild	No	Recovered	None	Yes
			Urogenital	RETENTION URINARY	URINE RETENTION	136	66	74	Mild	No	Recovered	None	Yes
231080	55/Female	RBX	Nervous	AGITATION	AGITATION	50	-55	15	Moderate	No	Recovered	None	No
				ANXIETY	JITTERINESS IN LATE AFTERNOON	50	2	15	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	50	0	36	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	50	0		Moderate	No	Not recovered	None	Yes
			Body	ABDOMINAL CRAMP	STOMACH CRAMPS	50	8		Mild	No	Not recovered	None	Yes
			Digestive	DIARRHEA	DIARRHEA	50	8	35	Mild	No	Recovered	None	Yes
			Special Senses	TASTE PERVERSION	STRANGE TASTE IN MOUTH	50	9	42	Moderate	No	Recovered	None	Yes

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231080	55/Female	RBX	Cardiovascular	CARDIAC RHYTHM ABNORMAL	CARDIAC ARRYTHMIA	50	-51		Moderate	No	Not recovered	None	No
			Body	HEADACHE	HEADACHES	50	13		Moderate	No	Not recovered	None	Yes
			Musculo-Skeletal	MUSCULAR WEAKNESS	MUSCLE FATIGUE TO ARMS	50	23		Moderate	No	Not recovered	None	No
			Urogenital	RETENTION URINARY	URINE RETENTION	50	22		Moderate	No	Not recovered	None	Yes
			Cardiovascular	VASODILATION	NIGHTLY HOT FLASHES	50	11		Mild	No	Not recovered	None	Yes
			Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS	50	30		Moderate	No	Not recovered	None	No
			Nervous	DIZZINESS	LIGHTHEADEDNESS	50	37		Mild	No	Not recovered	None	No
				CONCENTRATION IMPAIRED	DECREASED CONCENT-RATION	50	42		Moderate	No	Not recovered	None	No
				NERVOUSNESS	IRRITABILITY	50	43		Moderate	No	Not recovered	None	No
			Metabolic and Nutritional	PERIPHERAL EDEMA	EDEMA BOTH HANDS	50	38	40	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	50	28	40	Mild	No	Recovered	None	No
			Musculo-Skeletal	MUSCULAR WEAKNESS	MUSCLE FATIGUE TO LEGS	50	23		Moderate	No	Not recovered	None	No

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231119	56/Female	RBX	Nervous	ANXIETY	JITTERINESS	75		25	Mild	No	Recovered	None	No
			Body	ABDOMINAL DISTENSI-ON	BLOATING (ABDOMEN)	75		0	Moderate	No	Recovered	None	No
			Digestive	LOOSE STOOLS NEC	LOOSE STOOLS	75	1	14	Mild	No	Recovered	None	Yes
				FLATULENCE	FLATULENCE	75	1	25	Mild	No	Recovered	None	Yes
				THROAT DRY	DRY THROAT	75	1		Mild	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	NIGHT SWEATS	75	9	27	Moderate	No	Recovered	None	Yes
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	75	3		Mild	No	Not recovered	None	Yes
				NERVOUSNESS	IRRITABILITY	75	14		Moderate	No	Not recovered	None	Yes
				ANXIETY	ANXIETY	75	34		Moderate	No	Not recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	75	32		Moderate	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	INCREASED PERSPIR-ATION	75	33	48	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	75	35	35	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	75	35	35	Mild	No	Recovered	None	Yes

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Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
231119	56/Female	RBX	Body	ALLERGIC REACTION	INCREASED SEVERITY OF ALLERGY SYMPTO-MS	75	39	47	Moderate	No	Recovered with sequelae	None	No
			Special Senses	TASTE PERVERSION	BAD TASTE IN MOUTH	75	39		Mild	No	Not recovered	None	Yes
			Body	ABDOMINAL DISTENSI-ON	ABDOMINAL BLOATING	75	38		Mild	No	Not recovered	None	Yes
				LOCALIZED PAIN	LEG PAIN	75	6	6	Mild	No	Recovered	None	No
			Cardiovascular	VASODILATION	FLUSHED, BURNING SENSATION ON FACE	75	40	40	Mild	No	Recovered	None	No
231120	54/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	68			Severe	No	Not recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	68		54	Severe	No	Recovered	None	No
				ANXIETY	INCREASED ANXIETY	68	3	3	Mild	No	Recovered	None	No
				CHANGE IN DREAMS	VIVID DREAMS	68	10	12	Mild	No	Recovered	None	Yes
				ANXIETY	INCREASED ANXIETY	68	10	43	Mild	No	Recovered	None	No
			Body	HEADACHE	SINUS HEADACHE	68	7	26	Severe	No	Recovered	None	No
			Nervous	NERVOUSNESS	IRRITABILITY	68	3	3	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
231139	36/Female	RBX	Body	HEADACHE	INCREASED FREQUENCY HEADACHE	59	15	23	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	59		50	Moderate	No	Recovered	None	No
			Body	FLU SYNDROME	FLU SYMPTOMS	59	1	5	Mild	No	Recovered	None	No
				FATIGUE	FATIGUE	59	14	43	Moderate	No	Recovered	None	Yes
			Nervous	PARESTHESIA	RIGHT HAND TINGLING	59	15	23	Mild	No	Recovered	None	No
				CHANGE IN DREAMS	VIVID DREAMS	59	8		Moderate	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	59	10	43	Moderate	No	Recovered	None	Yes
			Body	ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	59	20	20	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	59	35	35	Moderate	No	Recovered	None	Yes
			Body	ABDOMINAL CRAMP	INTESTINAL CRAMPING	59	33	33	Moderate	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	59	34	35	Moderate	No	Recovered	None	Yes
241031	61/Male	RBX	Nervous	SOMNOLENCE	SEDATION	3	-93		Moderate	No	Not recovered	None	No
			Body	HEADACHE	HEADACHES	3	-6	0	Moderate	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
241031	61/Male	RBX	Body	ABDOMINAL CRAMP	STOMACH CRAMPS	3	1	3	Moderate	No	Recovered	Drug permanen-tly withdrawn	Yes
			Digestive	NAUSEA	NAUSEA	3	0	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
				CONSTIPATION	CONSTIPATION	3	1	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
			Nervous	INSOMNIA	INSOMNIA	3	0	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
				CONFUSION	CONFUSION	3	0	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
			Body	REACTION UNEVALUAB-LE	HEAVY STOMACH	3	0	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	3	1	3	Mild	No	Recovered	Drug permanen-tly withdrawn	Yes
241032	41/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	31		-1	Mild	No	Recovered	None	No
			Body	GENERALIZED EDEMA	INCREASED SEVERITY WATER RETENTION	31	5	8	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	LIGHT HEADED	31	8	8	Mild	No	Recovered	None	Yes
							14	14	Mild	No	Recovered	None	Yes

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241073	26/Female	RBX	Nervous	DIZZINESS	LIGHT HEADED	42	2		Mild	No	Not recovered	None	Yes
			Body	CHILLS	COLD CHILLS	42	2	5	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	42	21		Mild	No	Not recovered	None	Yes
			Nervous	NERVOUSNESS	INCREASED IRRITAB-ILITY	42	36		Mild	No	Not recovered	None	Yes
			Body	REACTION UNEVALUAB-LE	CONGESTION	42	11	11	Mild	No	Recovered	None	No
241074	21/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	42	1	13	Mild	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	42	1	18	Moderate	No	Recovered	None	Yes
			Cardiovascular	TACHYCARDIA	INCREASED HEART RATE	42	1	8	Mild	No	Recovered	None	Yes
			Body	HEADACHE	INCREASED SEVERITY OF HEADACHES	42	20		Moderate	No	Not recovered	None	Yes
				FLU SYNDROME	FLU LIKE SYMPTOMS	42	4	4	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	42	30	32	Mild	No	Recovered with sequelae	None	Yes
261023	33/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	56	0		Mild	No	Unknown	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
261023	33/Female	RBX	Body	BACK PAIN	BACKACHE	56	8	8	Moderate	No	Recovered	None	No
			Skin	RASH	RASH ON JAWLINE AND NECK	56	9	10	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	56	25	25	Mild	No	Recovered	None	Yes
							35	35	Moderate	No	Recovered	None	Yes
			Urogenital	INFECTION URINARY TRACT	URINARY TRACT INFECTION	56	27	90	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	56	27	27	Moderate	No	Recovered	None	Yes
					INTERMITTENT HEADACHES	56	41		Moderate	No	Unknown	None	Yes
			Cardiovascular	PALPITATION	HEART PALPITATIONS	56	44	44	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	56	44	44	Moderate	No	Recovered	None	No
			Special Senses	TINNITUS	TINNITUS	56	44	44	Moderate	No	Recovered	None	No
			Respiratory	PHARYNGITIS	SORE THROAT	56	95	99	Moderate	No	Recovered	None	No
			Body	FEVER	FEVER (INTERMITTE-NT)	56	95	97	Mild	No	Recovered	None	No
				FATIGUE	FATIGUE	56	97	97	Moderate	No	Recovered	None	No

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Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
261023	33/Female	RBX	Body	ABDOMINAL PAIN LOCALIZED	STOMACH ACHE	56	133	138	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	56	133	138	Mild	No	Recovered	None	No
271021	29/Male	RBX	Digestive	APPETITE DECREASED	DECREASED APPETITE	57	-14		Moderate	No	Not recovered	None	No
			Body	CHILLS	CHILLS	57	1	17	Moderate	No	Recovered	None	No
			Urogenital	EJACULATION ABNORM-AL	PAINFUL EJACULATI-ON	57	4	47	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	XEROSTOMA	57	7	14	Moderate	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHES	57	8	14	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	MIDDLE INSOMNIA	57	7	14	Moderate	No	Recovered	None	Yes
271022	42/Female	RBX	Respiratory	SINUSITIS	SINUS INFECTION	77	6	22	Moderate	No	Recovered	None	No
			Digestive	DRY MOUTH	DRY MOUTH	77	1		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHES	77	5	29	Moderate	No	Recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	77	7	29	Moderate	No	Recovered	None	Yes
				DIZZINESS	DIZZINESS	77	5	29	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
271022	42/Female	RBX	Digestive	RECTAL BLEEDING	BLOOD CLOT (RECTA-L)	77	16	17	Severe	No	Recovered	None	No
				DISORDER RECTAL	RECTAL SWELLING	77	17	34	Moderate	No	Recovered	None	No
				NAUSEA	NAUSEA	77	5	29	Moderate	No	Recovered	None	Yes
			Body	REACTION UNEVALUAB-LE	CRAMPING	77	36	60	Moderate	No	Recovered	None	No
				ABDOMINAL DISTENSI-ON	BLOATING	77	29	60	Moderate	No	Recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	77	42	73	Moderate	No	Recovered	None	No
			Body	ALLERGIC REACTION	FLU SHOT REACTION	77	62	64	Moderate	No	Recovered	None	No
			Special Senses	TINNITUS	TINNITUS	77	75		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	77	69		Mild	No	Not recovered	None	Yes
271045	18/Male	RBX	Nervous	INSOMNIA	INSOMNIA	38	2	8	Mild	No	Recovered	None	Yes
			Digestive	APPETITE DECREASED	DECREASED APPETITE	38	2		Mild	No	Not recovered	None	Yes
			Metabolic and Nutritional	WEIGHT DECREASE	WEIGHT LOSS	38	0	28	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	38	28		Moderate	No	Not recovered	None	Yes

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281025	41/Female	RBX	Nervous	INSOMNIA	INSOMNIA	3	0		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
				DIZZINESS	DIZZY	3	3		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
				ANXIETY	ANXIETY	3	3		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
			Digestive	CONSTIPATION	CONSTIPATION	3	3		Moderate	No	Not recovered	Drug permanen-tly withdrawn	Yes
281026	46/Female	RBX	Digestive	DRY MOUTH	DRY MOUTH	49	0		Moderate	No	Not recovered	None	Yes
			Nervous	NERVOUSNESS	IRRITABLE	49	5		Moderate	No	Not recovered	None	Yes
				INSOMNIA	INSOMNIA	49	5		Moderate	No	Not recovered	None	Yes
281101	40/Female	RBX	Cardiovascular	VASODILATION	HOT FLUSHES	56	1	3	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	56	1		Mild	No	Not recovered	None	Yes
			Nervous	INSOMNIA	INSOMNIA	56	19		Moderate	No	Not recovered	None	Yes
			Body	CHILLS	COLD FLASH	56	1	3	Mild	No	Recovered	None	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHES	56	24		Mild	No	Not recovered	None	No
281102	44/Female	Placebo	Cardiovascular	VASODILATION	HOT FLASH	68	0	28	Mild	No	Recovered	None	Yes

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
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281102	44/Female	Placebo	Nervous	PARESTHESIA	PARAESTHESIA	68	1	2	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	68	1	58	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	68	4	28	Mild	No	Recovered	None	Yes
			Digestive	CONSTIPATION	CONSTIPATION	68	6		Mild	No	Not recovered	None	Yes
			Urogenital	INFECTION URINARY TRACT	BLADDER INFECTION	68	5	10	Moderate	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZY	68	17	48	Mild	No	Recovered	None	Yes
			Body	TRAUMA	CHIPPED BONE OF LEFT GREAT TOE	68	15	35	Moderate	No	Recovered	None	No
				LOCALIZED PAIN	LEFT GREAT TOE PAIN	68	15	35	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	68	37	60	Mild	No	Recovered	None	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHES	68	59	62	Mild	No	Recovered	None	No
			Respiratory	RHINITIS	NASAL CONGESTION	68	59	65	Mild	No	Recovered	None	No
				COUGH	COUGH	68	59		Mild	No	Not recovered	None	No
			Body	CHILLS	COLD FLASH	68	0	28	Mild	No	Recovered	None	Yes

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281102	44/Female	Placebo	Nervous	DIZZINESS	DIZZY	68	66		Mild	No	Not recovered	None	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHES	68	66		Mild	No	Not recovered	None	Yes
			Body	HEADACHE	HEADACHE	68	67		Mild	No	Not recovered	None	Yes
			Digestive	NAUSEA	NAUSEA	68	67		Mild	No	Not recovered	None	Yes
281107	61/Female	RBX	Body	HEADACHE	HEADACHE	32	0		Moderate	No	Not recovered	None	Yes
			Skin	DIAPHORETIC	SWEATING	32	2		Mild	No	Not recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	32	0		Moderate	No	Not recovered	None	Yes
			Body	ABDOMINAL DISTENSI-ON	BLOATING	32	3		Mild	No	Not recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	32	0		Severe	No	Not recovered	None	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHE	32	17		Mild	No	Not recovered	None	No
				JOINT STIFFNESS	JOINT STIFFNESS	32	26		Mild	No	Not recovered	None	No
			Digestive	CONSTIPATION	CONSTIPATION	32	28		Mild	No	Not recovered	None	Yes
281108	53/Female	Placebo	Respiratory	PHARYNGITIS	SORE THROAT	91	3	4	Mild	No	Recovered	None	No
			Nervous	SOMNOLENCE	DROWSY	91	0	6	Mild	No	Recovered	None	Yes

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281108	53/Female	Placebo	Body	CHILLS	COLD FLASH	91	2	6	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASH	91	0	6	Mild	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	91	0	70	Mild	No	Recovered	None	Yes
				DYSPEPSIA	UPSET STOMACH	91	0	5	Mild	No	Recovered	None	Yes
			Body	HEADACHE	HEADACHE	91	10	70	Mild	No	Recovered	None	No
			Skin	DIAPHORETIC	SWEATING	91	7	46	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	HOT FLASH	91	8	30	Mild	No	Recovered	None	Yes
			Respiratory	BRONCHITIS	BRONCHITIS	91	14	30	Moderate	No	Recovered	None	No
				SINUSITIS	SINUS INFECTION	91	14	30	Moderate	No	Recovered	None	No
			Body	CHEST PAIN	CHEST TIGHTNESS	91	32	32	Mild	No	Recovered	None	No
			Nervous	INSOMNIA	INSOMNIA	91	40	82	Mild	No	Recovered	None	Yes
			Musculo-Skeletal	MYALGIA	MUSCLE ACHES	91	37	46	Mild	No	Recovered	None	Yes
			Cardiovascular	VASODILATION	FACIAL FLUSHING	91	49	70	Mild	No	Recovered	None	Yes
			Skin	DRY SKIN NON-APPLICATION SITE	DRY SKIN	91	53	70	Mild	No	Recovered	None	No

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281108	53/Female	Placebo	Body	LOCALIZED PAIN	RIGHT LEG ACHE	91	57		Mild	No	Not recovered	None	No
			Respiratory	PHARYNGITIS	SORE THROAT	91	58	62	Mild	No	Recovered	None	No
			Body	GENERALIZED PAIN	BODY ACHES	91	65		Mild	No	Not recovered	None	No
			Digestive	DYSPEPSIA	UPSET STOMACH	91	70	71	Mild	No	Recovered	None	No
311017	54/Male	RBX	Nervous	SOMNOLENCE	SEDATION	99	-94	7	Mild	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	99	6	6	Mild	No	Recovered	None	No
				BACK PAIN	LOWER BACK PAIN	99	9	10	Moderate	No	Recovered	None	No
				HEADACHE	HEADACHE	99	26	26	Mild	No	Recovered	None	No
			Digestive	NAUSEA	NAUSEA	99	26	28	Moderate	No	Recovered	None	No
				VOMITING	VOMITING	99	28	28	Mild	No	Recovered	None	No
				DYSPEPSIA	HEARTBURN	99	29	33	Moderate	No	Recovered	None	No
			Body	HEADACHE	HEADACHE	99	39	39	Moderate	No	Recovered	None	No
			Digestive	DYSPEPSIA	HEARTBURN	99	39	64	Severe	No	Recovered	None	No
			Urogenital	FREQUENCY URINARY	INCREASE FREQUENCY OF URINATION	99	43	51	Mild	No	Recovered	None	No

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311017	54/Male	RBX	Nervous	SOMNOLENCE	HYPERSOMNIA	99	36	51	Mild	No	Recovered	None	No
					AM SEDATION	99	62		Moderate	No	Not recovered	None	Yes
			Body	LOCALIZED PAIN	SHOULDER PAIN	99	74	74	Moderate	No	Recovered	None	No
							81		Moderate	No	Not recovered	None	No
			Nervous	PARESTHESIA	PARESTHESIA FINGER TIPS	99	78		Moderate	No	Not recovered	None	Yes
			Body	LOCALIZED PAIN	SHOULDER PAIN	99	81		Moderate	No	Not recovered	None	No
			Nervous	PARESTHESIA	PARESTHESIA FINGER TIPS	99	78		Moderate	No	Not recovered	None	Yes
311018	31/Female	RBX	Nervous	INSOMNIA	INCREASED INSOMNIA	64		1	Severe	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH	64		19	Mild	No	Recovered	None	No
			Body	TRAUMA	BACK STRAIN	64	29	35	Severe	No	Recovered	None	No
				UPPER RESPIRATORY INFECTION	COLD SYMPTOMS	64	48	52	Moderate	No	Recovered	None	No
				TRAUMA	MOTOR VEHICLE ACCIDENT	64	58	58	Moderate	No	Recovered	None	No

Note: * Treatment refers to the treatment assigned in the blinded medication phase. This information might not be relevant if the AE started and stopped before the end of open phase of the study.
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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
311115	30/Female	Placebo	Nervous	PARESTHESIA	PARESTHESIA TOP OF HEAD	113	1	14	Mild	No	Recovered	Dose reduced	Yes
			Cardiovascular	VASODILATION	HOT FLASHES	113	1	2	Mild	No	Recovered	Dose reduced	Yes
			Body	CHILLS	COLD FLASHES	113	1	2	Mild	No	Recovered	Dose reduced	Yes
			Nervous	DIZZINESS	DIZZINESS	113	1	1	Moderate	No	Recovered	Dose reduced	Yes
			Digestive	APPETITE DECREASED	LOSS OF APPETITE	113	1	44	Mild	No	Recovered	None	Yes
				DIARRHEA	DIARRHEA	113	11	11	Mild	No	Recovered	None	Yes
				STOMATITIS APHTHOUS	CANKER SORE	113	13	17	Mild	No	Recovered	None	No
			Body	BACK PAIN	LOWER BACK PAIN	113	17	19	Mild	No	Recovered	None	No
			Nervous	TREMOR	TREMULOUSNESS	113	1	72	Mild	No	Recovered	None	Yes
			Body	BACK PAIN	LOWER BACK PAIN	113	26	26	Mild	No	Recovered	None	No
			Nervous	DIZZINESS	DIZZINESS	113	26	44	Moderate	No	Recovered	None	Yes
			Body	CHEST PAIN	CHEST PAIN	113	23	23	Mild	No	Recovered	None	No
			Digestive	DYSPEPSIA	INDIGESTION	113	27	27	Mild	No	Recovered	None	No
				INCREASED THIRST	POLYDYPSIA	113	7	51	Moderate	No	Recovered	None	Yes

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LIST7

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
311115	30/Female	Placebo	Musculo-Skeletal	MYALGIA	MUSCLE ACHE IN LEG	113	38	38	Moderate	No	Recovered	None	No
			Nervous	CHANGE IN DREAMS	VIVID DREAMS	113	22	57	Moderate	No	Recovered	None	Yes
				DIZZINESS	DIZZINESS	113	57	64	Mild	No	Recovered	None	Yes
			Body	FATIGUE	FATIGUE	113	79	83	Mild	No	Recovered	None	Yes
311116	44/Female	RBX	Urogenital	MENOPAUSE	PREMENOPAUSAL SYMPTOMS		1	6	Moderate	No	Recovered	None	Yes
321055	38/Male	RBX	Digestive	DRY MOUTH	DRY MOUTH		1	3	Mild	No	Recovered	None	Yes
			Urogenital	DISORDER TESTICLE	TESTICULAR TIGHTN-ESS		3	4	Mild	No	Recovered	None	No
				EJACULATION ABNORM-AL	EJACULATORY DYSFUNCTION		4	5	Mild	No	Recovered	None	Yes
			Body	LOCALIZED PAIN	LUNG PAIN, BILATE-RAL		17	19	Moderate	No	Recovered	None	No
				ABDOMINAL PAIN LOCALIZED	STOMACH ACHE		17	17	Moderate	No	Recovered	None	Yes
			Digestive	DRY MOUTH	DRY MOUTH		20	20	Mild	No	Recovered	None	Yes
			Nervous	DIZZINESS	DIZZINESS		36	37	Mild	No	Recovered	None	Yes

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Adverse Events - Listing by Patient
All Enrolled Patients

Date Produced: January 15, 2001

Patient Number	Age/Sex	Trtmnt*	Body System	COSTART Term	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Max. Intensity	Ever Serious	Outcome	Action Taken	Drug Related
321055	38/Male	RBX	Digestive	NAUSEA	NAUSEA		36	37	Mild	No	Recovered	None	Yes
321056	44/Male	RBX	Digestive	DIARRHEA	DIARRHEA	8	7	8	Severe	No	Recovered	Drug permanen-tly withdrawn	Yes
			Urogenital	DISORDER TESTICLE	TESTICULAR REFRAC-TION	8	7	7	Moderate	No	Recovered	Drug permanen-tly withdrawn	Yes
				EJACULATION ABNORM-AL	SPONTANEOUS EJACULATION	8	7	7	Moderate	No	Recovered	Drug permanen-tly withdrawn	Yes
321087	55/Male	RBX	Urogenital	IMPOTENCE	ERECTILE DYSFUNCT-ION	171	8	61	Severe	No	Recovered	None	No
				RETENTION URINARY	URINARY RETENSION	171	8	31	Moderate	No	Recovered	None	Yes
			Musculo-Skeletal	CRAMP LEGS	LEG CRAMPS, BILATERAL, INTERM-ITTENT	171	33	46	Mild	No	Recovered	None	No
					LEG CRAMPS	171	110	110	Moderate	No	Recovered	None	No

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LIST8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

Date Produced: January 15, 2001

Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Amsterdam	11133	27JAN00	SHINGLES	2000/1/13	No	Severe	None	21FEB00	Recovered	No		
	11167	06APR00	HOT FLASHES	2000/3/18	No	Moderate	None		Not recovered	No	PROBABLY NOT RELATED TO PROZAC OR REBOXETINE	
Croft	231001	27SEP99	URINE RETENTION	1999/6/	No	Moderate	None		Not recovered	Yes	AFTER BEGINNING TREATMENT WITH PROZAC, URINARY RETENTION STARTED AT MODERATE INTENSITY THEN DECREASED TO MILD INTENSITY. THE INTENSITY INCREASED BACK TO MODERATE AFTER STARTING THE STUDY MEDICATION.	IT IS DR. CROFT-'S OPINION THAT THE URINE RETEN-TION WHILE ON PROZAC WAS RELATED TO THE PROZAC.
	231002	28OCT99	FATIGUE	1999/7/	No	Moderate	None		Not recovered	No	FATIGUE BEGAN AFTER STARTING PROZAC ON 6/29/99 AND WAS STILL PRESENT AT DAY 1 VISIT ON 10/28/99. FATIGUE WAS MILD ON 11/6 AND GETTING BETTER BUT DUE TO PINCHED NERVE AND MEDICATION FOR PAIN FATIGUE	GOT WORSE ON 11/9 STILL NOT STUDY DRUG RELATED.
	231080	14DEC99	AGITATION	1999/10/20	No	Moderate	None	29DEC99	Recovered	No	BEGAN AFTER STARTING PROZAC CONTINUES AT ENTRY INTO STUDY, PER PATIENT REPORT. IT'S DR.CROFT'S OPINION THAT AE WAS DUE TO PROZAC.	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

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Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Croft	231080	14DEC99	CARDIAC ARRYTHMIA	1999/10/24	No	Moderate	None		Not recovered	No	REPORTED AT WK3 VISIT THAT HAS HAD SKIPPED HEART BEATS WHICH WORSENED A COUPLE OF WEEKS AFTER STARTING PROZAC, TO MODERATE INTENSITY, AND STILL CONTINUE. POSSIBLY RELATED TO PROZAC	
	231119	07JAN00	JITTERINESS	1999/6/0	No	Mild	None	01FEB00	Recovered	No	BEGAN WITHIN FIRST COUPLE DAYS OF DOSING WITH PROZAC AND CONTINUES AT DAY 1 VISIT . IT IS DR.CROFT'S OPINION THAT JITTERINESS WAS RELATED TO PROZAC.	
		07JAN00	BLOATING (ABDOMEN)	1999/6/0	No	Moderate	None	07JAN00	Recovered	No	BEGAN WITHIN FIRST COUPLE DAYS OF STARTING PROZAC AND IS STILL PRESENT AT DAY 1 VISIT. IT IS DR.CROFT'S OPINION THAT THE BLOATING WAS RELATED TO PROZAC.	
	231120	20JAN00	DRY MOUTH	1999/7/	No	Severe	None		Not recovered	No	RELATED TO PROZAC PER PATIENT. IT IS DR.CROFT'S OPINION THAT AE WAS RELATED TO PROZAC CONTINUATION IS LIKELY DUE TO CONCURRENT ALLERGY MEDICATIONS.	PATIENT IS NOW IN 071 STUDY (THE EXTENSION STUDY) AS OF 03/27/00.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

Date Produced: January 15, 2001

Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Croft	231120	20JAN00	INSOMNIA	1999/7/	No	Severe	None	14MAR00	Recovered	No	RELATED TO PROZAC PER PATIENT. IT IS DR.CROFT'S OPINION THAT AE WAS RELATED TO PROZAC.	PATIENT IS NOW IN 071 STUDY (THE EXTENSION STUDY) AS OF 03/27/00.
	231139	14FEB00	INSOMNIA	1998/ /	No	Moderate	None	04APR00	Recovered	No	BEGAN WHEN STARTED PROZAC. PATIENT FEELS AE CAUSED BY PROZAC. IT IS DR. CROFT'S OPINION THAT THIS AE IS RELATED TO THE PROZAC.	
Delgado	41069	25OCT99	INCREASED APPETITE	1999/3/	No	Severe	None	01DEC99	Recovered	No	LAST DOSE OF PROZAC 10/24/99 . FIRST DOSE OF REBOXETINE 10/25/99. INCREASE IN APPETITE IMPROVED AFTER STARTING REBOXETINE. THEREFORE, INCREASED APPETITE MOST LIKELY RELATED TO PROZAC.	
		25OCT99	SEXUAL DYSFUNCTION	1999/3/	No	Severe	None	01DEC99	Recovered	No	LAST DOSE OF PROZAC 10/24/99 . FIRST DOSE OF REBOXETINE 10/25/99. SEXUAL DYSFUNCTION SIDE-EFFECT IMPROVED ON REBOXETINE. THEREFORE, THIS S.E. MOST LIKELY RELATED TO PROZAC.	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

Date Produced: January 15, 2001

Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Delgado	41070	05NOV99	SEXUAL DYSFUNCTION	1997/8/1	No	Moderate	None	27DEC99	Recovered	No	IN MY OPINION-THIS ADVERSE EFFECT IS RELATED TO PROZAC-SINCE IT IMPROVED ON REBOXETINE	
		05NOV99	DRY MOUTH	1999/5/	No	Severe	None		Not recovered	Yes	THIS ADVERSE EFFECT MOST LIKELY DUE TO PROZAC, SINCE IT IMPROVED ON REBOXETINE. PT. STATED EPISODE WAS WORSE THAN PRIOR DRY MOUTH EPISODES.	
	41093	15DEC99	ACID REFLUX	1999/11/1	No	Mild	None	16DEC99	Recovered	No	PT HAD PRIOR HISTORY OF GERD PRIOR TO THIS STUDY. REFLUX APPEARS RELATED TO FLUOXETINE AS IT RESULTED WHEN PROZAC STOPPED	
		15DEC99	EMOTIONAL BLUNTING	1999/12/1	No	Moderate	None	02JAN00	Recovered	No	PT HAD BLUNTING ON PROZAC PRIOR TO STARTING STUDY. RESOLVED ON REBOXETINE.	
		15DEC99	DIARRHEA	1999/12/13	No	Moderate	None	15DEC99	Recovered	No	PT REPORTS LONG HISTORY OF LOOSE STOOLS - IMPROVED SINCE STOPPED PROZAC	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
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Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Delgado	41094	23DEC99	ANXIETY	1999/11/25	No	Severe	None	07FEB00	Recovered	Yes	FIRST DOSE OF REBOXETINE WAS 12/15/99. ANXIETY INCREASED OFF PROZAC AND SLOWLY IMPROVED AFTER TAKING REBOXETINE UP. THEREFORE, POSSIBLY RELATED TO WITHDRAWAL OFF PROZAC.	
		23DEC99	SEXUAL DYSFUNCTION	1999/6/	No	Moderate	None	16JAN00	Recovered	No	SEXUAL DYSFUNCTION IMPROVED AFTER STOPPING PROZAC.	
DuBoff	311017	25OCT99	SEDATION	1999/7/23	No	Mild	None	01NOV99	Recovered	No	THE ABOVE AE IS POSSIBLY RELATED TO PROZAC	
	311018	15DEC99	INCREASED INSOMNIA	1987/ /	No	Severe	None	16DEC99	Recovered	Yes	AE PROBABLY RELATED TO PROZAC PRIOR TO 1999.12.15	
		15DEC99	DRY MOUTH	1987/ /	No	Mild	None	03JAN00	Recovered	No	PROBABLY RELATED TO PROZAC	
Dunner	211040	19OCT99	ELEVATED BLOOD PRESSURE	1999/10/8	No	Mild	None		Not recovered	No	PER PT REPORT, BP AT PRIVATE MD VISIT 12/7/99 WAS 120/70. ON 12/8/99 AT SCREEN VISIT WAS 146/90. SINCE THEN IT HAS FLUCTUATED BETWEEN 154-130/90-82. NOT RELATED TO PROZAC	
	211146	15FEB00	TINNITUS	1999/12/20	No	Mild	None	26FEB00	Recovered	No	PROZAC RELATED	

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Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

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Fava	51113	13JAN00	RIB INJURY	2000/1/2	No	Mild	None	20FEB00	Recovered	No	PROBABLY UNRELATED TO EITHER PROZAC, OR REBOXETINE (SIDE EFFECT STATED BEFORE PATIENT STARTED TAKING REBOXETINE)	
	51141	22FEB00	BODY SPASMS	1999/12/	No	Mild	None	11MAR00	Recovered	No	AE PRESENT DURING FLUOXETINE TREATMENT	
	51142	10MAR00	DRY MOUTH	1999/11/5	No	Moderate	None		Not recovered	Yes	DRY MOUTH IS LIKELY DUE BOTH TO PROZAC AND REBOXETINE	
		10MAR00	HEADACHES	1999/11/5	No	Mild	None	11MAR00	Recovered	No	AE PRESENT DURING FLUOXETINE TREATMENT	
		10MAR00	BODY SPASMS	1999/12/	No	Mild	None	11MAR00	Recovered	No	AE PRESENT DURING FLUOXETINE TREATMENT	
		10MAR00	INSOMNIA	1999/11/5	No	Mild	None	11MAR00	Recovered	No	AE PRESENT DURING FLUOXETINE TREATMENT	
		10MAR00	DROWSINESS	1999/11/5	No	Mild	None	11MAR00	Recovered	No	AE PRESENT DURING FLUOXETINE TREATMENT	
Ferguson	241031	08SEP99	SEDATION	1999/6/7	No	Moderate	None		Not recovered	No	THIS IS A SIDE EFFECT FROM PROZAC	
		08SEP99	HEADACHES	1999/9/2	No	Moderate	None	08SEP99	Recovered	Yes	PROZAC SIDE EFFECTS	
	241032	15SEP99	DRY MOUTH	1999/2/	No	Mild	None	14SEP99	Recovered	No	PROZAC SIDE EFFECT	
Helfing	81003	29JUN99	DRY MOUTH	1999/6/10	No	Moderate	None	29JUN99	Recovered	No	RELATED TO PROZAC	

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Helfing	81052	17SEP99	DRY MOUTH	1999/9/2	No	Mild	None	15OCT99	Recovered	No	RELATED TO PROZAC	
	81076	10NOV99	STREP THROAT	1999/11/6	No	Moderate	None	23NOV99	Recovered	No	POSSIBLE STREP THROAT, POSITIVE ERYTHEMA, PURULENT THROAT. NOT RELATED TO PROZAC	
		10NOV99	BODY ACHES	1999/11/6	No	Moderate	None	23NOV99	Recovered	No	NOT RELATED TO PROZAC	
		10NOV99	SEXUAL DYSFUNCTION	1999/6/	No	Mild	None		Not recovered	No	PER PI, RELATED TO PROZAC	
Hoopes	271021	15JUL99	DECREASED APPETITE	1999/7/1	No	Moderate	None		Not recovered	No	FELT TO BE PROZAC RELATED	
Liebowitz	91035	30AUG99	INCREASED SWEATING OF FACE	1999/8/24	No	Mild	None		Not recovered	No	AE NOT RELATED TO PROZAC OR STUDY DRUG	
	91097	20JAN00	FATIGUE	1999/12/7	No	Mild	None	15FEB00	Recovered	No	PROZAC RELATED AE	
	91137	31JAN00	HOT FLASH	2000/1/25	No	Moderate	None	25JAN00	Recovered	No	PROZAC RELATED AE	
		31JAN00	LOSS OF BALANCE	2000/1/25	No	Moderate	None	25JAN00	Recovered	No	PROZAC RELATED AE	
		31JAN00	FALL	2000/1/25	No	Moderate	None	25JAN00	Recovered	No	PROZAC RELATED AE	
		31JAN00	10 STITCHES ON HEAD	2000/1/25	No	Moderate	None	25JAN00	Recovered	No	PROZAC RELATED AE	
	91138	16MAR00	COLD SYMPTOMS	2000/3/11	No	Mild	None	27MAR00	Recovered	No	NOT A PROZAC RELATED AE	
Londborg	101009	09JUL99	DAYTIME FATIGUE	1999/1/5	No	Moderate	None	11JUL99	Recovered	No	PROZAC RELATED, PRIOR TO STUDY	

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Londborg	101010	21JUL99	CNS STIMULATION	1999/4/	No	Mild	Drug permanently withdrawn	07AUG99	Recovered	No	PROZAC RELATED	
		21JUL99	DECREASED LIBIDO	1999/1/	No	Mild	Drug permanently withdrawn		Not recovered	No	PROZAC RELATED	
	101044	07SEP99	NIGHT SWEATS	1999/5/	No	Moderate	None	27OCT99	Recovered	No	PROZAC RELATED	
		07SEP99	WEIGHT GAIN	1994/5/	No	Moderate	None	07SEP99	Recovered	No	PROZAC RELATED	
Lydiard	221034	28DEC99	HEADACHE	1999/12/23	No	Moderate	None	24DEC99	Recovered	No		
		28DEC99	FATIGUE	1999/12/21	No	Moderate	None		Not recovered	Yes	THERE IS A REASONABLE POSSIBILITY THAT EVENT IS RELATED TO PROZAC.	
McGrath	111057	10NOV99	NAUSEA	1999/10/5	No	Mild	None		Not recovered	No	PROZAC SIDE EFFECT	
		10NOV99	BELCHING	1999/10/5	No	Mild	None		Not recovered	No	PROZAC SIDE EFFECTS	
Munjack	131011	23SEP99	TRIGGER FINGER CORRECTIVE SURGERY	1999/ /	No	Severe	None	26FEB00	Recovered	No	PT UNAWARE OF WHEN THE ABOVE AE ACTUALLY OCCURRED; HE STARTED HAVING COMPLAINTS IN 1999 AND BELIEVES THAT LIFTING AND CARRYING HEAVY OBJECTS WITH (L) HAND HAS CAUSED IT.	
Rapaport	151037	19JUL99	LOSS OF LIBIDO	1996/ /	No	Mild	None		Not recovered	No	LOSS OF LIBIDO-POSSIBLY RELATED TO PROZAC TREATMENT	

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Rapaport	151037	19JUL99	VOMITTING	1996/ /	No	Mild	None	17AUG99	Recovered	No	INTERMITTENT VOMITTING-POSSIBLY RELATED TO PROZAC TREATMENT	
	151038	18OCT99	DROWSINESS	1999/9/7	No	Mild	None	29NOV99	Recovered	No	POSSIBLY REALTED TO PROZAC	
		18OCT99	DRY MOUTH	1999/9/7	No	Mild	None	08NOV99	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		18OCT99	PARESTHESIA	1999/9/7	No	Mild	None	18OCT99	Recovered	No	POSSIBLY RELATED TO PROZAC	
	151085	01NOV99	MUSCLE ACHE (BACK)	1999/10/30	No	Mild	None	14NOV99	Recovered	No	NOT RELATED TO PROZAC TREATMENT	
		01NOV99	LOSS OF LIBIDO	1994/ /	No	Mild	None		Not recovered	No	POSSIBLY REALTED TO PROZAC	
		01NOV99	DROWSINESS	1994/ /	No	Mild	None	08NOV99	Recovered	No	POSSIBLY RELATED TO PROZAC	
	151086	08NOV99	LOSS OF LIBIDO	1998/9/	No	Mild	None	10NOV99	Recovered	No	AE LIKELY DUE TO PROZAC	
		08NOV99	SHAKING	1999/11/2	No	Mild	None	29NOV99	Recovered	No	AE LIKELY DUE TO PROZAC.	
		08NOV99	DROWSINESS	1998/9/	No	Mild	None	29NOV99	Recovered	No	AE LIKELY DUE TO PROZAC	
	151095	09NOV99	NIGHT SWEATS	1999/8/	No	Mild	None	09NOV99	Recovered	No	AE POSSIBLY RELATED TO PROZAC	
	151099	24NOV99	LOSS OF LIBIDO	1999/8/20	No	Mild	None	04JAN00	Recovered	No	POSSIBLY RELATED TO PROZAC	
		24NOV99	DROWSINESS	1999/7/	No	Mild	None	07DEC99	Recovered	No	POSSIBLY RELATED TO PROZAC	
		24NOV99	SHAKING	1999/8/20	No	Mild	None	02DEC99	Recovered	No	POSSIBLY RELATED TO PROZAC	

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Rapaport	151100	08DEC99	HEARTBURN	1999/11/	No	Mild	None	11JAN00	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		08DEC99	DROWSINESS	1999/9/24	No	Mild	None	09DEC99	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		08DEC99	BLURRED VISION	1998/12/	No	Mild	None	11JAN00	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		08DEC99	RAPID HEART RATE	1999/10/	No	Mild	None	15DEC99	Recovered	No	POSSIBLY RELATED TO PROZAC	
	151118	10MAR00	CONSTIPATION	1999/12/15	No	Mild	None	07APR00	Recovered	Yes	POSSIBLY RELATED TO PROZAC AT BEGINNING OF STUDY, AND POSSIBLY RELATED TO STUDY DRUG DURING STUDY	
		10MAR00	URINARY HESITANCY	1999/12/15	No	Mild	None	07APR00	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		10MAR00	DELAYED EJACULATI-ON	1999/12/15	No	Mild	None	07APR00	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
		10MAR00	DRY MOUTH	1999/12/15	No	Mild	None	07APR00	Recovered	Yes	POSSIBLY RELATED TO PROZAC	
	151153	14MAR00	TOOTH PAIN	2000/3/8	No	Mild	None	28MAR00	Recovered	No	NOT LIKELY RELATED TO PROZAC TREATMENT.	
Thase	181083	17NOV99	VERY LOOSE BOWEL MOVEMENT	1999/11/12	No	Moderate	None	16NOV99	Recovered	No	NOT A COMPLAINT ON PROZAC ALONE	
	181084	18NOV99	HEARTBURN	1999/11/16	No	Mild	None	17NOV99	Recovered	No		
		18NOV99	SINUS PRESSURE	1999/11/15	No	Mild	None	11DEC99	Recovered	No	UNRELATED TO STUDY MEDS	
		18NOV99	SINUS PAIN	1999/11/15	No	Mild	None	11DEC99	Recovered	No	UNRELATED TO PROZAC	

LIST8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

Date Produced: January 15, 2001

Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Thase	181105	05JAN00	NIGHTMARES	1999/12/29	No	Moderate	None	04JAN00	Recovered	No	PT. ATTRIBUTES MIGHTMARES TO WITHDRAWL FROM WELLBUTRIN.	
Trivedi	191013	02AUG99	HEADACHE	1999/7/31	No	Moderate	None	31JUL99	Recovered	No	PT. HAS A HX. OF HEADACHES. INCREASE IN EPISODES WHEN TAKING PROZAC.(FROM DISCUSSION W/PT. ON 8/2/99).	RELATIONSHIP OF H/A TO PROZAC DOSE IS UNKNOWN.
Walsh	171015	30JUN99	INSOMNIA	1999/6/1	No	Mild	None		Not recovered	No	PROZAC RELATED	
		30JUN99	HEADACHE	1999/6/20	No	Mild	None	20JUN99	Recovered	No		
	171062	12OCT99	INSOMNIA	1999/8/1	No	Moderate	None	21NOV99	Recovered	No	PROZAC RELATED	
	171063	18OCT99	FEELING TIRED	1997/6/1	No	Moderate	None	29OCT99	Recovered	No	PROZAC RELATED	
		18OCT99	LOSS OF SEX DRIVE	1997/6/1	No	Moderate	None	18DEC99	Recovered	No	PROZAC RELATED	
Zajecka	201068	22OCT99	ELEVATED LIVER ENZYMES	1999/10/11	No	Mild	None	07JAN00	Recovered	No	PROBABLE IDIOSYNCRATIC REACTION TO FLUOXETINE WILL FOLLOW TO SEE IF LFT'S NORMALIZE OFF FLUOXETINE	
	201091	02DEC99	DECREASED LIBIDO	1994/3/	No	Moderate	None		Not recovered	No	DECREASED LIBIDO PRECEDED INITIATION OF STUDY DRUG DECREASED LIBIDO POSSIBLY RELATED TO PROZAC INITIATION	
		02DEC99	MUSCLE STRAIN UNDER LEFT BREAST	1999/11/25	No	Severe	None		Not recovered	No	PHYSICAL INJURY UNRELATED TO STUDY DRUG.	

LIST8

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Adverse Events Which Started before Day One Visit and Continued after Day One
All Enrolled Patients

Date Produced: January 15, 2001

Inv.	Patient Number	Day 1 Date	AE Description	Start Date	Ever Serious	Max. Intensity	Action Taken	Stop Date	Outcome	Rel. to Study Drug	Comment	Additional Comment
Zajecka	201092	22FEB00	INSOMNIA	2000/1/12	No	Moderate	None	24MAR00	Recovered	No	INSOMNIA PRESENT PRIOR TO PROZAC USAGE	
		22FEB00	SLEEPLESSNESS	2000/1/12	No	Mild	None	24MAR00	Recovered	No		
	201123	22FEB00	TIREDNESS	2000/1/25	No	Mild	None		Not recovered	No	PRESENT WHILE ON PROZAC AND BEFORE ADMIN OF REBOXETINE	

LIST9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Adverse Events
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Treatment*	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Comment	Additional Comment
Delgado	41069	RBX	BILATERAL ANKLE EDEMA	71	63		PT HAD VIRAL INFECTION AT TIME. EDEMA RESOLVED AFTER VIRAL INFECTION RESOLVED. EDEMA WAS NON PITTING. MOST LIKELY NOT SECONDARY TO REBOXETINE	PT. SAW HER PCP AND HE ADVISES THAT HER SX'S COULD BE A VIRAL INFECTION
			JOINT PAIN (BILATERAL WRIST)	71	58		HAD VIRAL INFECTION. PT. SAW HER PCP AND HE ADVISES THAT HER SX'S COULD BE A VIRAL INFECTION.	
			FEVER	71	61	61	FEVER WENT ALONG WITH JOINT PAIN AND ANKLE SWELLING. PT'S DOCTOR THINKS SHE HAS SOME KIND OF VIRUS BUT ISN'T SURE. RESOLVED AFTER VIRUS RAN IT'S COURSE. PT REPORTED HER TEMPERATURE WAS 101 DEGREES.	
			BILATERAL KNEE JOINT PAIN	71	58		OCCURED DURING VIRAL INFECTION. PT. SAW HER PCP AND HE ADVISES THAT HER SX'S COULD BE A VIRAL INFECTION	
			BILATERAL ANKLE JOINT PAIN	71	58		PT HAD VIRAL INFECTION. PT. SAW HER PCP AND HE ADVISES THAT HER SX'S COULD BE A VIRAL INFECTION.	

Note: *Treatment is the treatment assigned in the blinded medication phase.
Day of last dose, onset day, stop date are relative to baseline day.

LIST9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Adverse Events
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Treatment*	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Comment	Additional Comment
Delgado	41093	RBX	CONFUSION	72	61	62	OCCURED AFTER BEGINNING BLINDED PHASE - HAS HAPPENED WITH HER DEPRESSION PRIOR.	
			FATIGUE	72	60	60	C/O LOW ENERGY PRIOR TO STARTING REBOXETINE AS EVIDENCED BY THE MADRAS AND IS NOT RELATED TO REBOXETINE.	
				72	63	67	C/O LOW ENERGY PRIOR TO STARTING REBOXETINE AS EVIDENCED BY THE MADRAS AND IS NOT RELATED TO REBOXETINE.	
Helfing	81076	RBX	DISLOCATED 2 RIBS - LEFT SIDE	171	98	133	SECONDARY TO LIFTING PATIENT WHILE AT WORK	
Munjack	131125	Placebo	POST-OP PAIN (L) BREAST	74	66	68	NO HOSPITALIZATION	
Thase	181084	Placebo	MYALGIA, HANDS	120	67	81	INJURY AT WORK	
			MYALGIA, ARMS	120	67	81	INJURY AT WORK	
Trivedi	191014	RBX	PREMATURE EJACULATION	156	89		SUBJECT UNABLE TO BE CONTACTED FOR FOLLOW-UP.	

Note: *Treatment is the treatment assigned in the blinded medication phase.
Day of last dose, onset day, stop date are relative to baseline day.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Adverse Events
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Treatment*	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Comment	Additional Comment
Trivedi	191014	RBX	BRAIN TUMOR	156	159		PATIENT HAS DECLINED FURTHER FOLLOW UP TO THIS SAE. SEE SAE CRF.	
Dunner	211109	RBX	HEADACHE	78	62	72	OCCURRED 2 DAYS AFTER RANDOMIZATION AND HAS HAPPENED EVERY DAY SINCE. REQUIRED IBUPROFEN	
	211110	Placebo	INSOMNIA	78	66	66	PT. DISTURBED DUE TO SHOWING FAMILY HOME FOR SALE - DIFFICULTY SLEEPING.	
Croft	231001	RBX	CHEST PAIN	128	97	107	SUBJECT TO SEE CARDIOLOGIST FOR CONSULT, SUBJECT DESCRIBES AS "CHEST TWINGES".	
			INCREASED NERVOUSNESS	128	109	112	PT. STATES THIS EVENT COULD BE DUE TO OVER WORKING	
			ELEVATED BLOOD PRESSURE	128	70		SUBJECT TO CARDIOLOGIST FOR EVALUATION OF AE, AFTER SPEAKING WITH CARDIOLOGIST, DR. CROFT HAS DECIDED AE IS NOT RELATED TO STUDY MEDICATION	

Note: *Treatment is the treatment assigned in the blinded medication phase.
Day of last dose, onset day, stop date are relative to baseline day.

LIST9

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments on Adverse Events
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Treatment*	AE Verbatim	Day of L.D.	Onset Day	Stop Day	Comment	Additional Comment
Prover	261023	RBX	STOMACH ACHE	56	133	138	THIS INFORMATION OBTAINED ONLY BY PATIENT DIARY. PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO DISCUSS/CONFIRM	
			NAUSEA	56	133	138	THIS INFORMATION OBTAINED ONLY BY PATIENT DIARY PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO DISCUSS/CONFIRM	
Oldroyd	321087	RBX	LEG CRAMPS	171	110	110	PATIENT HAS HISTORY OF OCCASIONAL LEG CRAMPS PRECEDING THE STUDY	

Note: *Treatment is the treatment assigned in the blinded medication phase.
Day of last dose, onset day, stop date are relative to baseline day.

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Amsterdam	11065	59/Male	AMOXICILLIN	AMOXICILLIN	21	40		GINGIVITIS	101-AMOXICILLIN TAKEN PRIOR IN CONJUCTION W/ GUM SURGERY ; 103-TAKEN FOR GUM SURGERY-NO ADDITIONAL INFO. AVAILABLE	
			VIAGRA	VIAGRA	13		Ongoing	IMPOTENCE	101-AMOXICILLIN TAKEN PRIOR IN CONJUCTION W/ GUM SURGERY ; 103-TAKEN FOR GUM SURGERY-NO ADDITIONAL INFO. AVAILABLE	
			TYLENOL W/CODEINE NO. 3	TYLENOL 3	28	44		PAIN	101-AMOXICILLIN TAKEN PRIOR IN CONJUCTION W/ GUM SURGERY ; 103-TAKEN FOR GUM SURGERY-NO ADDITIONAL INFO. AVAILABLE	
			PERCOCET	PERCOCET	28	44		PAIN	104-TAKEN FOR GUM SURGERY (1 /12/00)-NO ADDITIONAL INFO. AVAILABLE.	
			ZOCOR	ZOCOR			Ongoing	HYPERCHOLESTER-OLEMIA	104-TAKEN FOR GUM SURGERY (1 /12/00)-NO ADDITIONAL INFO. AVAILABLE.	
	11066	56/Male		AVACOR	8		Ongoing	HYPERTENSION		
			CLARITIN	CLARITIN	1		Ongoing	ALLERGIES		
			DYAZIDE	DIAZIDE	23		Ongoing	HYPERTENSION		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Amsterdam	11133	41/Male	FAMVIR	FAMUIR	-12	-6		SHINGLES		
			CEFTIN	CEFTIN	-12	-6		SHINGLES		
			PERCOCET	PERCOCET	-12	-5		SHINGLES		
			ADVIL	ADVIL	-4	25		SHINGLES		
			LEVAQUIN	LEVAQUIN	10	22		SINUS INFECTION		
			PREDNISONE (DELTA-CORTISONE)	PREDNISONE	10	22		SINUS INFECTION		
			ZYRTEC	ZYRTEC	46			ALLERGIES		
			DURATUSS	DURATUSS	46			CHEST CONGESTI-ON		
			PREDNISONE (DELTA-CORTISONE)	PREDNISONE	62		Ongoing	SINUS INFECTION		
	11159	48/Female	CENTRUM	CENTRUM	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			GINKGO BILOBA	GINKGO BILOBA	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			FOLIC ACID (FOLAC-IN)	FOLIC ACID	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			CHROMIUM PICOLINA-TE	CHROMIUM PICOLI-NATE	-6		Ongoing	NUTRITIONAL SUPPLEMENT		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Amsterdam	11159	48/Female		E-400	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			CALTRATE	CALTRATE 600+	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			STRESS FORMULA	STRESS FORMULA VITAMIN	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			VITAMIN B6	B-6	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			VITAMIN B12 W/ VITAMIN B COMPLEX	B COMPLEX W/ B-12	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			BIOTIN	BIOTIN	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			EVENING PRIMROSE OIL	EVENING PRIMROSE OIL	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			HOMEOPATHIC MEDICINE	FLAX-OIL	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
			LACTOBACILLUS ACIDOPHILUS	ACIDOPHILUS	-6		Ongoing	NUTRITIONAL SUPPLEMENT		
	11167	53/Female	STEROID MEDICATION	STEROID	33	33		PAIN		
				PREVACOL	42			HYPERCHOLESTER-OLEMIA		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Barbee	21053	30/Male	PROPECIA	PROPECIA		44		HAIRLOSS		
			IMODIUM	IMMODIUM	4	13		INTESTIONAL VIRUS		
			BENADRYL SYSTEMIC	BENADRYL	14	14		HAY FEVER		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	34	34		MUSCLE PAIN-BACK		
Clayton	31019	45/Male	IBUPROFEN	IBUPROFEN			Ongoing	COSTOCHONDRITIS (CHRONIC)		
			MAALOX PLUS	MAALOX PLUS	2	5		ACID INDIGESTI-ON		
					8		Ongoing	ACID INDIGESTI-ON		
			PSEUDOEPHEDRINE HCL	PSUDOEPHEDRINE HCL	28		Ongoing	SINUS CONGESTI-ON		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	35		Ongoing	COSTOCHONDRITIS		
			TUMS	TUMS	15		Ongoing	ACID INDIGESTI-ON		
			ROLAIDS	ROLAIDS	72		Ongoing	ACID INDIGESTI-ON		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Clayton	31020	55/Male	ZOLPIDEM TARTRATE	ZOLPIDEM TARTRA-TE	7	33		INSOMNIA	LINE 003- DOSE AMOUNT IS 7.5 TO 15 MG (1 OR 2 TABS) PRN	
			TYLENOL	TYLENOL	1	224		HEADACHE	LINE 003- DOSE AMOUNT IS 7.5 TO 15 MG (1 OR 2 TABS) PRN	
			RESTORIL	RESTORIL	35		Ongoing	INSOMNIA	LINE 003- DOSE AMOUNT IS 7.5 TO 15 MG (1 OR 2 TABS) PRN	
			CONTAC-12 HOUR	CONTAC 12-HOUR CAPLETS	40	41		HEAD COLD		
	31047	27/Female	ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT		
			CALCIUM	CALCIUM			Ongoing	SUPPLEMENT		
			ZOLPIDEM TARTRATE	ZOLPIDEM TARTRA-TE	7		Ongoing	INSOMNIA		
	31048	46/Female	VITAMIN B1 (THIAM-INE HCL)	VITAMIN B			Ongoing	SUPPLEMENT		
			VITAMIN C	VITAMIN C			Ongoing	SUPPLEMENT		
			IBUPROFEN	IBUPROFEN	1		Ongoing	HEADACHE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Clayton	31048	46/Female	CEPHALEXIN	CEPHALEXIN	4	11		PROPHYLAXIS FOR INFECTION	004-PT IS HAVING A CHEMICAL PEEL PROCEDURE DONE ON HER FACE TODAY AND THE CEPHALEXIN IS TO HELP PREVENT INFECTION.12/23/99-UPDATE: PT NOTIFIED ME SHE	HAD LASER TREATME-NT INSTEAD OF A CHEMICAL PEEL ON HER FACE.
			EXCEDRIN	EXCEDRIN	14		Ongoing	HEADACHE	004-PT IS HAVING A CHEMICAL PEEL PROCEDURE DONE ON HER FACE TODAY AND THE CEPHALEXIN IS TO HELP PREVENT INFECTION.12/23/99-UPDATE: PT NOTIFIED ME SHE	HAD LASER TREATME-NT INSTEAD OF A CHEMICAL PEEL ON HER FACE.
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	42		Ongoing	HEADACHE	004-PT IS HAVING A CHEMICAL PEEL PROCEDURE DONE ON HER FACE TODAY AND THE CEPHALEXIN IS TO HELP PREVENT INFECTION.12/23/99-UPDATE: PT NOTIFIED ME SHE	HAD LASER TREATME-NT INSTEAD OF A CHEMICAL PEEL ON HER FACE.
	31111	37/Female	AMBIEN	AMBIEN	0	3		INSOMNIA		
			ZITHROMAX	ZITHROMAX	8	8		BRONCHITIS		
					9	11		BRONCHITIS		
			LEVAQUIN	LEVAQUIN	21		Ongoing	BRONCHITIS	004- PATIENT WILL TAKE THIS MED UNTIL 4/21/00 (10 DAYS)	
	31112	44/Female	SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Clayton	31112	44/Female	TYLENOL EXTRA STRENGTH	TYLENOL EXTRA STRENGTH	5	5		BACKACHE		
			ALLEGRA	ALLEGRA	39	43		SEASONAL ALLER-GIES		
			BACTRIM DS	BACTRIM DS 800-160	44	53		SINUSITIS		
Croft	231001	50/Female	MULTIVITAMINS	MULTIVITAMIN	-210		Ongoing	NUTRITIONAL SUPPLEMENT		
			VITAMIN C	VITAMIN C	-210		Ongoing	NUTRITIONAL SUPPLEMENT		
			VITAMIN B COMPLEX	B COMPLEX	-210	104		NUTRITIONAL SUPPLEMENT		
			CALCIUM WITH/ MAGNESIUM	CALCIUM/MAGNESI-UM	-210		Ongoing	NUTRITIONAL SUPPLEMENT		
			GARLIC	GARLIC	-210	104		NUTRITIONAL SUPPLEMENT		
			GLUCOSAMINE SULPHATE	GLUCOSAMINE	-210	16		NUTRITIONAL SUPPLEMENT		
			SELENIUM W/VITAMIN E	VITAMIN E & SELENIUM	6	104		NUTRITIONAL SUPPLEMENT		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Croft	231001	50/Female	CEPHALEXIN	CEPHALEXIN	21	28		FACIAL EXCORIATION	010-FOOD ENZYME IS A COMBINATION OF CALCIUM 200MG, PHOSPHORUS 160MG, BETAINE HCL 324MG, CREATINE 44MG, MYCOZYME 80MG, PEPSIN 90MG, PEPSIN 120MG,	LIPASE 30IU, BROHELAINE 100MG & BILE 50HG 80MG
			CIPRO	CIPRO	28	35		FACIAL EXCORIATION	010-FOOD ENZYME IS A COMBINATION OF CALCIUM 200MG, PHOSPHORUS 160MG, BETAINE HCL 324MG, CREATINE 44MG, MYCOZYME 80MG, PEPSIN 90MG, PEPSIN 120MG,	LIPASE 30IU, BROHELAINE 100MG & BILE 50HG 80MG
			ENZYME NOS	FOOD ENZYME	-210	104		NUTRITIONAL SUPPLEMENT	010-FOOD ENZYME IS A COMBINATION OF CALCIUM 200MG, PHOSPHORUS 160MG, BETAINE HCL 324MG, CREATINE 44MG, MYCOZYME 80MG, PEPSIN 90MG, PEPSIN 120MG,	LIPASE 30IU, BROHELAINE 100MG & BILE 50HG 80MG
			HOMEOPATHIC MEDICINE	FLAX SEED OIL	35	104		NUTRITIONAL SUPPLEMENT	010-FOOD ENZYME IS A COMBINATION OF CALCIUM 200MG, PHOSPHORUS 160MG, BETAINE HCL 324MG, CREATINE 44MG, MYCOZYME 80MG, PEPSIN 90MG, PEPSIN 120MG,	LIPASE 30IU, BROHELAINE 100MG & BILE 50HG 80MG
			CO-Q-10 (COENZYME Q10)	MEGA CO ENZYME Q	35	99		NUTRITIONAL SUPPLEMENT		
			KLONOPIN	KLONOPIN	39	40		INSOMNIA		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Croft	231001	50/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	42	42		COLD SYMPTOMS		
			TYLENOL	TYLENOL	43	43		COLD SYMPTOMS		
			NUTRITIONAL SUPPLEMENT	BON-C NUTRITION-AL SUPPLEMENT	53	77		NUTRITIONAL SUPPLEMENT	BON-C IS A COMBINATION OF MULLEIN LEAVES, PLANTAIN HERB, YARROW FLOWER AND REHMANNIA ROOT	
			VERSED	VERSED	52	52		ABDOMINAL LIPO-SUCTION	BON-C IS A COMBINATION OF MULLEIN LEAVES, PLANTAIN HERB, YARROW FLOWER AND REHMANNIA ROOT	
			DEMEROL	DEMEROL	52	52		ABDOMINAL LIPO-SUCTION	BON-C IS A COMBINATION OF MULLEIN LEAVES, PLANTAIN HERB, YARROW FLOWER AND REHMANNIA ROOT	
			VICODIN	VICODIN	52	52		ABDOMINAL LIPO-SUCTION	BON-C IS A COMBINATION OF MULLEIN LEAVES, PLANTAIN HERB, YARROW FLOWER AND REHMANNIA ROOT	
			KEFLEX	KEFLEX	51	51		ABDOMINAL LIPO-SUCTION	023 CONTAINS BONE SET HERB, HORSE RADDISH ROOT, MULLEIN LEAVES, FENNEL SEEDS, AND FENUGREEK SEEDS.	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Croft	231001	50/Female	KEFLEX	KEFLEX	52	56		ABDOMINAL LIPO-SUCTION	023 CONTAINS BONE SET HERB, HORSE RADDISH ROOT, MULLEIN LEAVES, FENNEL SEEDS, AND FENUGREEK SEEDS.	
			TYLENOL	TYLENOL	71	71		HEADACHE	023 CONTAINS BONE SET HERB, HORSE RADDISH ROOT, MULLEIN LEAVES, FENNEL SEEDS, AND FENUGREEK SEEDS.	
			NUTRITIONAL SUPPLEMENT	ALJ NUTRITIONAL SUPPLEMENT	108		Ongoing	NUTRITIONAL SUPPLEMENT	023 CONTAINS BONE SET HERB, HORSE RADDISH ROOT, MULLEIN LEAVES, FENNEL SEEDS, AND FENUGREEK SEEDS.	
			HOMEOPATHIC MEDICINE	CAYANNE	77	104		NUTRITIONAL SUPPLEMENT		
				HAWTHORN BERRIES	77	104		NUTRITIONAL SUPPLEMENT		
	231002	40/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		
			CALCIUM	CALCIUM			Ongoing	NUTRITIONAL SUPPLEMENT		
			HYDROCODONE	HYDROCODONE	11		Ongoing	SCIATIC NERVE IRRITATION		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Croft	231002	40/Female	SKELAXIN	SKELAXIN	11	14		SCIATIC NERVE IRRITATION	#007: 4MG TABS, TOOK 6 THE 1ST DAY, 5 THE 2ND DAY, 4 THE 3RD DAY, 3 THE 4TH DAY, 2 THE 5TH DAY AND 1 THE 6TH DAY.	
			RELAFEN	RELAFEN	11	20		SCIATIC NERVE IRRITATION	#007: 4MG TABS, TOOK 6 THE 1ST DAY, 5 THE 2ND DAY, 4 THE 3RD DAY, 3 THE 4TH DAY, 2 THE 5TH DAY AND 1 THE 6TH DAY.	
			VALIUM	VALIUM	14		Ongoing	SCIATIC NERVE IRRITATION	#007: 4MG TABS, TOOK 6 THE 1ST DAY, 5 THE 2ND DAY, 4 THE 3RD DAY, 3 THE 4TH DAY, 2 THE 5TH DAY AND 1 THE 6TH DAY.	
			MEDROL TABLETS	MEDROL	15	20		SCIATIC NERVE IRRITATION	#007: 4MG TABS, TOOK 6 THE 1ST DAY, 5 THE 2ND DAY, 4 THE 3RD DAY, 3 THE 4TH DAY, 2 THE 5TH DAY AND 1 THE 6TH DAY.	
			IBUPROFEN	IBUPROFEN	20	25		SCIATIC NERVE IRRITATION	CON MED. #011 COMBINATION 1000 MG ACETOMINOPHEN AND 25 MG DYPHENHYDIENNE HCL	
			ETODOLAC	ETODOLAC	25		Ongoing	SCIATIC NERVE IRRITATION	CON MED. #011 COMBINATION 1000 MG ACETOMINOPHEN AND 25 MG DYPHENHYDIENNE HCL	

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Croft	231002	40/Female	CIMETIDINE	CIMETIDINE	1	4		HEARTBURN	CON MED. #011 COMBINATION 1000 MG ACETOMINOPHEN AND 25 MG DYPHENHYDIENNE HCL	
			TYLENOL ALLERGY SINUS NIGHT TIME, MAXIMUM STRENGTH	TYLENOL ALLERGY AND SINUS	5	5		ALLERGIES	CON MED. #011 COMBINATION 1000 MG ACETOMINOPHEN AND 25 MG DYPHENHYDIENNE HCL	
			TUMS	TUMS	5	5		HEARTBURN	SUBJECT RECEIVED 6 INJECTIONS OF UNKNOWN MEDICATION FOR PAIN RELIEF (3 INJECTIONS ON 11/09/99 AND 3 ON 11/14/99). WE WERE UNABLE TO GET NAME OF	MEDICATION FROM SUBJECT, PCP, OR ER
			IBUPROFEN	IBUPROFEN	4	4		HEADACHE	SUBJECT RECEIVED 6 INJECTIONS OF UNKNOWN MEDICATION FOR PAIN RELIEF (3 INJECTIONS ON 11/09/99 AND 3 ON 11/14/99). WE WERE UNABLE TO GET NAME OF	MEDICATION FROM SUBJECT, PCP, OR ER
	231079	65/Male	LOTENSIN	LOTENSIN	57		Ongoing	HYPERTENSION	#001 SUBJECT HAS EXPERIENCED B/P FLUCTUATIONS SINCE 1988, HIS PHYSICIAN GAVE HIM AN ANTIHYPERTENSIVE FOR A WHILE , BUT THEN STOPPED IT BECAUSE HE	(THE MD)FELT IT WAS NO LONGER NEEDED.SUBJECT HAD NOT BEEN ON B/P MEDS FOR SEVERAL YEARS AND FLUCTIO-NS CONTINUED,NEW PHYSICIAN RECENTLY STARTED ON MEDS

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Croft	231080	55/Female	ESTRACE	ESTRACE	-1E3		Ongoing	HORMONE REPLAC-EMENT THERAPY	#003 SUBJECT BREAKS TAVIST 1 .34MG TABLET INTO QUARTERS, TAKES 0.25 OF TABLET EACH DOSE	
			MULTIVITAMINS	MULTIVITAMINS	-196		Ongoing	NUTRITIONAL SUPPLEMENT	#003 SUBJECT BREAKS TAVIST 1 .34MG TABLET INTO QUARTERS, TAKES 0.25 OF TABLET EACH DOSE	
			TAVIST	TAVIST	2		Ongoing	SEASONAL ALLER-GIES	#003 SUBJECT BREAKS TAVIST 1 .34MG TABLET INTO QUARTERS, TAKES 0.25 OF TABLET EACH DOSE	
			EXCEDRIN EXTRA STRENGTH	EXCEDRIN EXTRA STRENGTH	1		Ongoing	SINUS HEADACHE	005-SUBJECT INSTRUCTED NOT TO USE EXCEDRIN PM DURING STUDY PARTICIPATION, OK TO USE EXCEDRIN EXTRA STRENGTH	
			EXCEDRIN PM	EXCEDRIN PM	3	5		SINUS HEADACHE	005-SUBJECT INSTRUCTED NOT TO USE EXCEDRIN PM DURING STUDY PARTICIPATION, OK TO USE EXCEDRIN EXTRA STRENGTH	
			TITRALAC	TITRALAC	15	18		HEARTBURN	005-SUBJECT INSTRUCTED NOT TO USE EXCEDRIN PM DURING STUDY PARTICIPATION, OK TO USE EXCEDRIN EXTRA STRENGTH	

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Croft	231080	55/Female	TAGAMET	TAGAMET	18		Ongoing	HEARTBURN	005-SUBJECT INSTRUCTED NOT TO USE EXCEDRIN PM DURING STUDY PARTICIPATION, OK TO USE EXCEDRIN EXTRA STRENGTH	
			NAPROXEN	NAPROXEN	40	43		BACK PAIN		
			ALEVE	ALEVE	35	43		BACK PAIN		
	231119	56/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		
			CALCIUM	CALCIUM			Ongoing	NUTRITIONAL SUPPLEMENT		
			PREMARIN	PREMARIN			Ongoing	HORMONE REPLAC-EMENT		
			ACTIFED	ACTIFED	0		Ongoing	SINUS HEADACHE DUE TO ALLERGI-ES		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	0		Ongoing	SINUS HEADACHE DUE TO ALLERGI-ES		
			NASACORT	NASACORT AQ	40		Ongoing	ALLERGIES		
			ALLEGRA-D	ALLEGRA-D	40		Ongoing	ALLERGIES		
			CLEAR EYES	CLEAR EYES	46		Ongoing	ALLERGIES		

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Croft	231119	56/Female	ALCOHOL (ETOH)	WINE	23	23		SOCIAL		
				DAIQUIRI	34	34		SOCIAL		
				WINE	34	34		SOCIAL		
			RESTORIL	RESTORIL	21	22		INSOMNIA		
	231120	54/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	SUPPLEMENT	PATIENT NOW IN 071 EXTENSION STUDY	
			ATROVENT	ATROVENT			Ongoing	SEASONAL ALLER-GIES	PATIENT NOW IN 071 EXTENSION STUDY	
			IBUPROFEN	IBUPROFEN			Ongoing	NECK PAIN	PATIENT NOW IN 071 EXTENSION STUDY	
			ALLEGRA-D	ALLEGRA-D			Ongoing	SEASONAL ALLER-GIES	PATIENTS ALTERNATES BETWEEN ALLEGRA-D AND SEPTRA. PATIENT NOW IN 071 EXTENSION STUDY. #006-DURATUS HAS A COMBINATION OF PSEUDOEPHEDR-INE HCL 100MG AND	600MG OF GUAINFEN-ESIN PER TAB.
			SEPTRA	SEPTRA		36		PREVENTION OF INFECTION DUE TO SEASONAL ALLERGIES	PATIENTS ALTERNATES BETWEEN ALLEGRA-D AND SEPTRA. PATIENT NOW IN 071 EXTENSION STUDY. #006-DURATUS HAS A COMBINATION OF PSEUDOEPHEDR-INE HCL 100MG AND	600MG OF GUAINFEN-ESIN PER TAB.

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Croft	231120	54/Female	DURATUSS	DURATUSS			Ongoing	SEASONAL ALLERGIES	PATIENTS ALTERNATES BETWEEN ALLEGRA-D AND SEPTRA. PATIENT NOW IN 071 EXTENSION STUDY. #006-DURATUS HAS A COMBINATION OF PSEUDOEPHEDRINE HCL 100MG AND	600MG OF GUAINFENESIN PER TAB.
			NASONEX	NASONEX		20		SEASONAL ALLERGIES	PATIENTS ALTERNATES BETWEEN ALLEGRA-D AND SEPTRA. PATIENT NOW IN 071 EXTENSION STUDY. #006-DURATUS HAS A COMBINATION OF PSEUDOEPHEDRINE HCL 100MG AND	600MG OF GUAINFENESIN PER TAB.
			BENADRYL SYSTEMIC	BENADRYL	2	2		SEASONAL ALLERGIES		
			SUDAFED	SUDAFED	17	27		SEASONAL ALLERGIES		
			AMBIEN	AMBIEN	7	53		INSOMNIA		
			FLONASE	FLONASE	20		Ongoing	SEASONAL ALLERGIES	PATIENT NOW IN 071 EXTENSION STUDY	
			SUDAFED	SUDAFED	36	42		SEASONAL ALLERGIES	PATIENT NOW IN 071 EXTENSION STUDY	
			ROBAXIN	ROBAXIN	31	31		NECK PAIN		
			CORRECTOL	CORRECTOL	34	34		EPISODES CONSTIPATION		

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Croft	231139	36/Female	AFRIN	AFRIN			Ongoing	ALLERGIES		
			MULTIVITAMINS	MULTIVITAMINS			Ongoing	SUPPLEMENT		
			ADVIL	ADVIL			Ongoing	HEADACHES		
			EXTRA STRENGTH TYLENOL PM	TYLENOL PM	-6	-6		INSOMNIA		
			RESTORIL	RESTORIL	2		Ongoing	INSOMNIA		
			PSEUDOEPHEDRINE HCL	PSEUDOEPHEDRINE HCL	15	53		HEADACHE		
			PEPTO BISMOL	PEPTO BISMOL	33	33		INTESTINAL CRAMPING		
			RESTORIL	RESTORIL	2		Ongoing	INSOMNIA		
Delgado	41069	41/Female	SUDAFED	SUDAFED	-3E3	50		ALLERGIES	TOMY PAIN PRESCRIBED 11/1/99 15MG + 1/2+ QHS. PT DOES NOT AND HAS NOT TAKEN ANY.	
			CLARITIN D/LORATADINE W/PSEUDOEPHEDRINE SULPHATE	CLARITIN D	-2E3	50		ALLERGIES	TOMY PAIN PRESCRIBED 11/1/99 15MG + 1/2+ QHS. PT DOES NOT AND HAS NOT TAKEN ANY.	
			ZOVIRAX SYSTEMIC	ZOVARIX	-3E3	50		COLD SORES	TOMY PAIN PRESCRIBED 11/1/99 15MG + 1/2+ QHS. PT DOES NOT AND HAS NOT TAKEN ANY.	
			IBUPROFEN	IBUPROFEN	-3E3		Ongoing	HEADACHE		

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Delgado	41069	41/Female	KEFLEX	KEFLEX	8	13		PRE-OP MEDICAT-ION (FOR CUT WRIST REPAIR)		
			AUGMENTIN	AUGMENTIN	42	53		SINUS/EAR INFE-CTION (DUE TO SEASONAL ALLER-GIES)		
	41070	46/Female	PREMARIN	PREMARIN			Ongoing	HYSTERECTOMY		
			SYNTHROID	SYNTHROID	-8E3		Ongoing	HYPOTHYROID		
			ADVIL	ADVIL	-1	-1		HEADACHE		
			TYLENOL	TYLENOL	3		Ongoing	HEADACHE		
			ADVIL	ADVIL	2		Ongoing	HEADACHE		
			TUMS	TUMS	2		Ongoing	ACID REFLUX		
			MOTRIN TABLETS	MOTRIN	3		Ongoing	HEADACHE		
			MYLANTA	MYLANTA	16	16		CHEST PRESSURE	009 PT HAD DOGS AMOXICILLIN IN HER HAND, WENT TO TAKE A DRINK AND ACCIDENTALLY TOOK DOGS PILL. 008 PT C/O CHEST PRESSURE THAT WAS NOT LIKE HER OTHER	ACID REFLUX SO SHE TOOK 1 DOSE OF MYLANTA. SHE EXPLAINED IT AS A WEIGHT ON HER CHEST.

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Delgado	41070	46/Female	AMOXICILLIN	AMOXICILLIN	21	21		ACCIDENTALLY TAKEN IN ERROR	009 PT HAD DOGS AMOXICILLIN IN HER HAND, WENT TO TAKE A DRINK AND ACCIDENTALLY TOOK DOGS PILL. 008 PT C/O CHEST PRESSURE THAT WAS NOT LIKE HER OTHER	ACID REFLUX SO SHE TOOK 1 DOSE OF MYLANTA. SHE EXPLAINED IT AS A WEIGHT ON HER CHEST.
	41093	56/Female	CLARITIN	CLARITIN	-14		Ongoing	ALLERGIES		
			MULTIVITAMINS	WALGREEN'S A-Z MULTIVITAMIN	-14		Ongoing	DIETARY SUPPLE-MENT		
			EXCEDRIN	EXCEDRIN	-14		Ongoing	HEADACHES		
			TYLENOL COLD MEDICATION	TYLENOL COLD	7	11		FLU SYMPTOMS		
			GLUTATHIONE	PIRBUTEROL ACETATE INHALER	21	22		ASTHMA		
			ADVIL	ADVIL	27	27		HEADACHES		
			TYLENOL	TYLENOL	8	26		HEADACHES		
	41094	64/Female	ESTRADERM	ESTRADERM PATCH			Ongoing	HORMONES		
			ADVIL	ADVIL	1	17		HEADACHES		
			ALKA SELTZER PLUS COLD TABLETS	ALKASELTZER COLD PLUS	4	13		COLD SYMPTOMS		

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Delgado	41094	64/Female	TUMS	TUMS CALCIUM SUPPLEMENT			Ongoing	PREVENTATIVE		
			PEPCID AC	PEPCID AC	8	8		HEARTBURN		
			TYLENOL EXTRA STRENGTH	TYLENOL EXTRA STRENGTH	13	13		HEADACHE		
			AMBIEN	AMBIEN	14	31		SLEEP AIDE		
			VANCENASE NASAL INHALER	VANCENASE	15	42		NASAL CONGESTI-ON		
			SODIUM CHLORIDE NASAL	SALINE NASAL SPRAY	15	50		NASAL CONGESTI-ON		
			ADVIL	ADVIL	20	20		LEG ACHE		
			AMBIEN	AMBIEN	32	34		SLEEP AIDE		
			RESTORIL	RESTORIL	51	59		SLEEP AIDE		
			XANAX TABLETS	XANAX	9	10		ANXIETY		
DuBoff	311017	54/Male	PREVACID	PREVACID			Ongoing	HIATAL HERNIA		
			TYLENOL EXTRA	EXTRA STRENGTH	9	10		LOWER BACK PAIN		
			STRENGTH	TYLENOL	28	29		SHOULDER PAIN SECONDARY TO ROTATOR CUFF SURGERY		

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DuBoff	311017	54/Male	VICODIN	VICODIN	25	27		SHOULDER PAIN SECONDARY TO ROTATOR CUFF SURGERY		
			DIPRIVAN	DIPRIVAN	25	25		ANESTHESIA FOR ROTATOR CUFF SURGERY		
			ALKA SELTZER	ALKA SELTZER	32	33		HEARTBURN		
			TYLENOL EXTRA STRENGTH	EXTRA STRENGTH TYLENOL	39	39		HEADACHE		
			ALKA SELTZER	ALKA SELTZER	39	42		HEARTBURN		
			SODIUM CHLORIDE (NORMAL SALINE, ISOTONIC,0.9%, NACL)	SALINE	25	25		ROTATOR CUFF SURGERY		
			MARCAINE W/EPINEP-HRINE	0.5% MARCAINE WITH EPINEPHRINE	25	25		ROTATOR CUFF SURGERY		
			MARCAINE W/XYLOCA-INE (LIDOCAINE)	0.5% MARCAINE;2% XYLOCAINE W/O	25	25		ROTATOR CUFF SURGERY		
			CELEBREX/CELECOXIB	CELEBREX	-6	1		TORN ROTATOR CUFF PAIN		
			TUMS	TUMS	43		Ongoing	HEARTBURN		

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DuBoff	311017	54/Male	PROPULSID	PROPULSID	51	52		HEARTBURN		
					59		Ongoing	HEARTBURN		
			VICODIN	VICADIN	69	69		SHOULDER PAIN		
			TYLENOL EXTRA	EXTRA STRENGTH	74	74		SHOULDER PAIN		
			STRENGTH	TYLENOL	81	83		SHOULDER PAIN		
					86	87		SHOULDER PAIN		
					91	95		SHOULDER PAIN		
	311018	31/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		
			MINOCYCLINE	MINOCYCLINE			Ongoing	ACNE		
			FLEXERIL	FLEXERIL	29	35		PAIN SECONDARY TO BACK STRAIN		
			VICODIN	VICODIN	29	29		PAIN SECONDARY TO BACK STRAIN		
			IBUPROFEN	IBUPROFEN	30	35		PAIN SECONDARY YO BACK STRAIN		
			NORPLANT SYSTEM	NORPLANT			Ongoing	CONTRACEPTION		
			ECHINACEA(PURPLE CONEFLOWER)	ECHINACEA	49	52		COLD SYMPTOMS		

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DuBoff	311018	31/Female	VITAMIN C	VITAMIN C	49	52		COLD SYMPTOMS		
			THERAFLU FLU & COLD MEDICINE	THERA FLU, FLU AND COLD	50	50		COLD SYMPTOMS		
	311115	30/Female	IBUPROFEN	IBUPROFEN			Ongoing	TENSION HEADAC-HES		
			NECON/ORTHO-NOVUM	NECON		53		BIRTH CONTROL		
			IBUPROFEN	IBUPROFEN		53		MENSTRUAL CRAM-PS		
			AMBIEN	AMBIEN	5	5		INSOMNIA		
					2	2		INSOMNIA		
					7	15		INSOMNIA		
			MULTIVITAMINS	MULTI-VITAMIN	11		Ongoing	NUTRITIONAL SUPPLEMENT		
			AMBIEN	AMBIEN	20		Ongoing	INSOMNIA		
			IBUPROFEN	IBUPROFEN	14	15		CANKER SORE		
			EXCEDRIN	EXCEDRIN MIGRAI-NE	26	26		HEADACHE		
			CLARITIN	CLARITIN	23	23		HAYFEVER		
			BUTALBITAL	BUTALBITAL	28	28		HEADACHE		

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DuBoff	311115	30/Female	TUMS	TUMS	27	27		INDIGESTION		
			IBUPROFEN	IBUPROFEN	38	38		MUSCLE ACHE IN LEG		
			DEPO-PROVERA CONTRACEPTIVE INJ.	DEPO PROVERA	53		Ongoing	BIRTH CONTROL		
			IMITREX/SUMATRIPT-AN	IMITREX	62	62		MIGRAINE HEADA-CHE		
			BUTALBITAL	BUTALBITAL	102	102		HEADACHE		
			LIDEX	LIDEX			Ongoing	PSORIASIS		
	311116	44/Female	ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT THERAPY	IT IS UNKNOWN WHETHER CON MEDS ARE STOPPED OR ONGOING AS SUBJECT IS LOST TO FOLLOWUP	
			IMITREX/SUMATRIPT-AN	IMITREX			Ongoing	MIGRAINE HEADA-CHE	IT IS UNKNOWN WHETHER CON MEDS ARE STOPPED OR ONGOING AS SUBJECT IS LOST TO FOLLOWUP	
			AMBIEN	AMBIEN	-36		Ongoing	INSOMNIA	IT IS UNKNOWN WHETHER CON MEDS ARE STOPPED OR ONGOING AS SUBJECT IS LOST TO FOLLOWUP	

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DuBoff	311116	44/Female	TYLENOL ALLERGY SINUS NIGHT TIME, MAXIMUM STRENGTH	TYLENOL ALLERGY AND SINUS	2	2		SINUS CONGESTI-ON		
			EXCEDRIN	EXCEDRIN MIGRAI-NE	2	2		MIGRAINE HEADA-CHE		
			ANACIN	ANACIN	2	2		SINUS HEADACHE		
					9	9		MIGRAINE HEADA-CHE		
Dunner	211039	53/Female	ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT THERAPY	002: MEDROXYPROGESTERONE TAKEN FIRST 12 DAYS OF EACH MONTH	
			MEDROXYPROGESTERO-NE ACETATE	MEDROXYPROGESTE-RONE			Ongoing	HORMONE REPLAC-EMENT THERAPY	002: MEDROXYPROGESTERONE TAKEN FIRST 12 DAYS OF EACH MONTH	
			DIPHENHYDRAMINE	DIPHENHYDRAMINE	8	50		WORSE INSOMNIA	002: MEDROXYPROGESTERONE TAKEN FIRST 12 DAYS OF EACH MONTH	
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	15	15		HEADACHE		
	211040	53/Female	PROPRANOLOL	PROPRANANOL			Ongoing	PREVENTION OF MIGRAINE HEADA-CHES		
			SUMATRIPTAN	SUMATRYPTIN			Ongoing	MIGRAINES		

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Dunner	211040	53/Female	DIMETAPP	DIMETAPP			Ongoing	NASAL CONGESTI-ON		
			TYLENOL	TYLENOL			Ongoing	MUSCLE ACHES		
	211109	43/Male	ROLAIDS	ROLAIDS	0		Ongoing	INDIGESTION		
			IBUPROFEN	IBUPROFEN	65	72		HEADACHE		
	211110	54/Female	TRIAMTERENE W/ HYDROCHLOROTHIAZI-DE (HCTZ)	TRIAMTERENE/HCTZ			Ongoing	HYPERTENSION		
			PROVERA	PROVERA			Ongoing	HORMONE REPLAC-EMENT THERAPY		
			PREMARIN	PREMARIN			Ongoing	HORMONE REPLAC-EMENT THERAPY		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	4	4		HEADACHE	LINE #007 HAD AN "UPSETTING DAY"	
			CONTAC	CONTAC	21	23		RHINITIS	LINE #007 HAD AN "UPSETTING DAY"	
					30	32		RHINITIS	LINE #007 HAD AN "UPSETTING DAY"	
			TYLENOL	TYLENOL	66	66		TO SLEEP	LINE #007 HAD AN "UPSETTING DAY"	

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Dunner	211145	41/Male	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	-30		Ongoing	HEADACHE		
			AMBIEN	AMBIEN	1		Ongoing	INSOMNIA		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	9	20		PRN RHINITIS		
	211146	57/Male	BENADRYL SYSTEMIC	BENADRYL	8	9		RHINITIS		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	0	0		HEADACHE		
			TYLENOL	TYLENOL	55	55		HEADACHE		
			ZOCOR	ZOCAR	53		Ongoing	HYPERCHOLESTER-OLEMIA		
	211147	37/Female	EXCEDRIN	EXCEDRIN	2	5		HEADACHE		
			VENLAFAXINE	VENLAFAXINE	9		Ongoing	MAJOR DEPRESSI-ON		
			VISTARIL	VISTARIL	8	9		ANXIETY		
			GABAPENTIN	GABAPENTIN	9	12		UNK		
Fava	51113	55/Female	TYLENOL W/CODEINE NO. 3	TYLENOL 3	-14	-1		COLD S/S AND MUSCLE PAIN		
			IBUPROFEN	IBUPROFEN	19	20		DENTAL WORK		

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Concomitant Medication - Patient Listing
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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Fava	51113	55/Female	ZESTORETIC	ZESTORETIC	46		Ongoing	HYPERTENSION		
	51114	54/Female	BIAXIN	BIOXIN	10	12		UPPER RESPIRATORY INFECTION		
			COMPAZINE	COMPAZINE	10	12		NAUSEA		
			AMBIEN	AMBIEN	15		Ongoing	INSOMNIA		
			CONTAC	CONTACT	7	36		SINUSITIS		
	51141	30/Female	MIRCETTE/DESOGESTREL W/ETHINYL ESTRADIOL	MIRCETTE-28			Ongoing	ORAL CONTRACEPTIVES	01) DESOGESTREL/ETNINYL, EXTRADIOL AND ETHNINYL ESTRADIOL	
			EXCEDRIN	EXCEDRIN MIGRAINE			Ongoing	HEADACHES	01) DESOGESTREL/ETNINYL, EXTRADIOL AND ETHNINYL ESTRADIOL	
			EXTRA STRENGTH TYLENOL PM	TYLENOL PM			Ongoing	HEADACHES	01) DESOGESTREL/ETNINYL, EXTRADIOL AND ETHNINYL ESTRADIOL	
			AMBIEN	AMBIEN	-14		Ongoing	INSOMNIA		
			MOTRIN TABLETS	MOTRIN			Ongoing	MUSCLE SPASM		
	51142	44/Female	MACROBID	MACROBID			Ongoing	RECURRENT URINARY TRACT INFECTIONS		
			TYLENOL	TYLENOL			Ongoing	HEADACHES		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Fava	51142	44/Female	MOTRIN TABLETS	MOTRIN	14		Ongoing	HEEL PAIN		
Ferguson	241031	61/Male	ASPIRIN (ACETYLSALICYLIC ACID,ASA)	ASPIRIN			Ongoing	STROKE PREVENTION		
			PRINIVIL	PRINIVIL			Ongoing	HIGH BLOOD PRESSURE		
			PROZAC	PROZAC	3		Ongoing	DEPRESSION		
	241032	41/Female	ESTRACE	ESTRACE	-987		Ongoing	HORMONE REPLACEMENT		
			MAXZIDE	MAXIDE	-987		Ongoing	WATER RETENTION		
			ADVIL	ADVIL	-4E3		Ongoing	HEADACHES		
	241073	26/Female	VITAMIN B1 (THIAMINE HCL)	VITAMIN B			Ongoing	SUPPLEMENT		
			VITAMIN C	VITAMIN C			Ongoing	SUPPLEMENT		
			MULTIVITAMINS	MULTI-VITAMIN			Ongoing	SUPPLEMENT		
			ASPIRIN (ACETYLSALICYLIC ACID,ASA)	ASPIRIN			Ongoing	MIGRAINES		
			ACETAMINOPHEN(APAP)	ACETAMINOPHEN			Ongoing	MIGRAINES		
			IMITREX/SUMATRIPTAN	IMITREX			Ongoing	MIGRAINES		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Ferguson	241073	26/Female	VITAMIN B1 (THIAMINE HCL)	VITAMIN B				SUPPLEMENT		
			VITAMIN C	VITAMIN C				SUPPLEMENT		
			MULTIVITAMINS	MULTI-VITAMIN				SUPPLEMENT		
	241074	21/Female	IBUPROFEN	IBUPROFEN			Ongoing	HEADACHES		
			METAMUCIL	METAMUCIL			Ongoing	IRRITABLE BOWEL		
			NORPLANT SYSTEM	NORPLANT			Ongoing	BIRTH CONTROL		
			COMTREX	COMTREX	4	4		FLU LIKE SYMPTOMS		
				FENDOL	31	31		ALLERGIES		
			ALLERGY MEDICATION	PERFECT CHOICE ALLERGY TALBETS	31	31		ALLERGIES		
			COMTREX	COMTREX	31	31		ALLERGIES		
Gilmer	61081	45/Female	IBUPROFEN	IBUPROFEN			Ongoing	R KNEE PAIN		
			CARDIZEM	CARDIZEM	0		Ongoing	RAYNAUD'S DISEASE		
	61082	56/Female	PEPCID AC	PEPCID AC			Ongoing	ACID REFLUX		
			CLARITIN	CLARITIN			Ongoing	SEASONAL RHINITIS		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Gilmer	61082	56/Female	ADVIL	ADVIL			Ongoing	BACK PAIN		
			CALCIUM	CALCIUM			Ongoing	HEALTH MAINTEN-ANCE		
			MULTIVITAMINS	MULTIVITAMIN			Ongoing	HEALTH MAINTEN-ANCE		
			VITAMIN E	VITAMIN E			Ongoing	HEALTH MAINTEN-ANCE		
			ESTROGEN	ESTROGEN PATCH			Ongoing	HORMONE REPLAC-EMENT		
Halbreich	71077	56/Female	CALAN	CALAN			Ongoing	VASCULAR HEADA-CHES		
			CELEBREX/CELECOXIB	CELEBREX			Ongoing	ARTHRITIS		
			HYDROCHLOROTHIAZI-DE (HCTZ)	HCTZ			Ongoing	HYPERTENSION		
			CLIMARA	CLIMARA PATCH			Ongoing	POST MENOPAUSE		
			DARVOCET-N	DARVOCET			Ongoing	ARTHRITIS		
			CORRECTOL	CORRECTOL	6		Ongoing	CONSTIPATION		
			FIBERALL	FIBERALL	12		Ongoing	CONSTIPATION		
			MIDRIN	MIDRIN	21	21		VASCULAR HEADA-CHE		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Halbreich	71077	56/Female	COLACE	COLACE	22		Ongoing	CONSTIPATION		
			ATARAX	ATARAX	44	49		INSOMNIA		
Helfing	81003	65/Female	SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM		
			PREMARIN	PREMARIN			Ongoing	HORMONE REPLAC-EMENT		
			VITAMIN E	VITAMIN E			Ongoing	HEALTH SUPPLEM-ENT		
			CALCIUM	CALCIUM			Ongoing	HEALTH SUPPLEM-ENT		
			GLUCOSAMINE SULPHATE	GLUCOSAMINE			Ongoing	ARTHRITIS		
			CITRUCEL	CITRUCEL			Ongoing	IRRITABLE BOWEL SYNDROME		
			MULTIVITAMINS	MULTIVITAMIN			Ongoing	HEALTH SUPPLEM-ENT		
			CELEBREX/CELECOXIB	CELEBREX	53	56		PAIN RELATED TO FALL		
			TEMAZEPAM	TEMAZEPAM	52		Ongoing	INSOMNIA		
			CIPRO	CIPRO	56		Ongoing	BRONCHITIS		
			TEMAZEPAM	TEMAZEPAM	4	7		INSOMNIA		

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Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Helfing	81003	65/Female	EXCEDRIN	EXCEDRIN	40	40		HEADACHE		
					43	44		TENSION HEADAC-HES		
	81004	43/Female	TEMAZEPAM	TEMAZEPAM	5		Ongoing	INSOMNIA		
			ADVIL	ADVIL	22	22		HEADACHE		
					28	29		HEADACHE		
					38	38		HEADACHE		
			MOTRIN TABLETS	MOTRIN	40	40		HEADACHE		
			TYLENOL	TYLENOL	46	46		MIGRAINE HEADA-CHE		
			ADVIL	ADVIL	49	49		HEADACHE		
					53	54		HEADACHE		
					66	66		HEADACHE		
	81051	37/Female	CLOBETASOL PROPIO-NATE	CLOBETASOL			Ongoing	ECZEMA		
			HYDROCORTISONE (CORTISOL)RECTAL	HYDROCORTISONE ENEMAS	-9		Ongoing	IRRITABLE BOWEL DISEASE		
			LEVSIN	LEVSIN	-31		Ongoing	IRRITABLE BOWEL DISEASE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Helfing	81051	37/Female	DICYCLOMINE	DICYCLOMINE	1	20		IRRITABLE BOWEL DISEASE		
			CHITOSAN/GLUCOSAMINE	CHITOSAN FIBER EXTRACT	14		Ongoing	CONSTIPATION		
			OCUHIST	OCCUHIST EYE DROPS	15		Ongoing	ALLERGIC REACTION TO YARD		
			HERBAL MEDICINE	HERBAL SUPPLEMENT	16		Ongoing	AID ENDURANCE		
	81052	39/Female	AMBIEN	AMBIEN	4	4		INSOMNIA		
			MOTRIN TABLETS	MOTRIN	1		Ongoing	HEADACHE		
			VICODIN	VICODIN	-18	-16		LOW BACK PAIN		
	81075	37/Female	MIGRAINE MEDICINE	MIGRAINE ICE PADS			Ongoing	MIGRAINE		
			NAPROSYN	NAPROSYN	33	33		HEADACHE		
			TYLENOL MAXIMUM STRENGTH SINUS	TYLENOL SINUS	46	47		UPPER RESPIRATORY INFECTION		
			VICKS DAYQUIL	DAYQUIL	46	47		UPPER RESPIRATORY INFECTION		
			TYLENOL	TYLENOL	46	46		UPPER RESPIRATORY INFECTION		

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Concomitant Medication - Patient Listing
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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Helfing	81075	37/Female	TYLENOL MAXIMUM STRENGTH SINUS	TYLENOL SINUS	82	83		FLU SYMPTOMS		
			COTYLENOL	CO-TYLENOL	82	83		FLU SYMPTOMS		
			TRIAMINIC	TRIAMINIC	110	112		UPPER RESPIRAT-ORY INFECTION		
			ADVIL	ADVIL	109	109		UPPER RESPIRAT-ORY INFECTION		
	81076	23/Female	DEPO-PROVERA CONTRACEPTIVE INJ.	DEPO PROVERA			Ongoing	BIRTH CONTROL		
			AUGMENTIN	AUGMENTIN	0	5		SORE THROAT		
					7	13		SORE THROAT		
			ADVIL	ADVIL	14	16		BACK SPASMS		
			VIOXX/ROFECOXIB	VIOXX	14	16		BACK SPASMS		
					25	25		BACK PAIN		
			ADVIL	ADVIL	36	36		HEADACHE		
			NYQUIL LIQUICAPS	NYQUIL	0	0		SORE THROAT(ST-REP)		
			THERAFLU FLU & COLD MEDICINE	THERA-FLU	45	57		UPPER RESPIRAT-ORY INFECTION		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Helfing	81076	23/Female	THERAFLU FLU & COLD MEDICINE	THERAFLU	63	65		UPPER RESPIRATORY INFECTION		
			AMBIEN	AMBIEN	36		Ongoing	INSOMNIA		
			IBUPROFEN	IBUPROFEN	98	99		DISLOCATED RIBS		
					104	104		DISLOCATED RIBS		
			VIOXX/ROFECOXIB	VIOXX	99	100		DISLOCATED RIBS		
			TYLENOL W/CODEINE NO. 3	TYLENOL 3	101	101		DISLOCATED RIBS		
			ALEVE	ALEVE	102	103		DISLOCATED RIBS		
			IBUPROFEN	IBUPROFEN	135	139		GUM INFECTION		
			PROPOXYPHENE NAPSYLATE W/ ACETAMINOPHEN	PROPO-N/APA	136	139		GUM INFECTION		
			AMOXICILLIN	AMOXICILLIN	139	139		PROPHYLAXIS		
			VEETIDS	VEETIDS	137	139		GUM INFECTION		
	81103	48/Female	VICODIN	VICODIN	-1E3		Ongoing	NECK PAIN		
			SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM		
			ALLEGRA-D	ALLEGRA-D			Ongoing	SEASONAL ALLERGIES		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Helfing	81103	48/Female	PREMARIN	PREMARIN			Ongoing	HORMONE REPLACEMENT THERAPY		
			ZANTAC	ZANTAC	5	7		NAUSEA		
			PRILOSEC (LOSEC)	PRILOSEC	7	15		NAUSEA		
			FIBERCON	FIBERCON	7		Ongoing	CONSTIPATION		
			PEPTO BISMOL	PEPTO BISMOL	2	2		NAUSEA		
			AMBIEN	AMBIEN	3		Ongoing	INSOMNIA		
			ALKA SELTZER	ALKA SELTZER	5	6		NAUSEA		
			ADVIL	ADVIL	10	10		HEADACHE		
					13	13		HEADACHE		
					19	19		BACK OF LEGS ACHE		
			NYQUIL LIQUICAPS	NYQUIL	43	43		UPPER RESPIRATORY INFECTION		
			AUGMENTIN	AUGMENTIN	53	59		VIRAL UPPER RESPIRATORY INFECTION		
Hoopes	271022	42/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Hoopes	271022	42/Female	VITAMIN E	VITAMIN E			Ongoing	NUTRITIONAL SUPPLEMENT		
			ADVIL	ADVIL			Ongoing	MENSTRUAL CRAMPS		
			BACTRIM DS	BACTRIM DS	6	16		SINUS INFECTION		
			ADVIL	ADVIL	14	14		HEADACHES		
			FIORICET	FIORICET	14	22		HEADACHES		
			PREPARATION H	PREPARATION H	16	17		BLOOD CLOT (RECTAL)		
			HYDROCORTISONE (CORTISOL)TOPICAL	HYDROCORTISONE CREAM 2.5%	17	34		RECTAL SWELLING		
			FIBER	NATURAL FIBER THERAPY	17	49		NUTRITIONAL SUPPLEMENT		
			DIUREX	DIUREX			Ongoing	MENSTRUAL BLOATING		
			FIBERCON	FIBERCON	49		Ongoing	CONSTIPATION		
			FLU(INFLUENZA) VACCINE	FLU SHOT	59	59		FLU PROPHYLAXIS		
	271045	18/Male	TEMAZEPAM	TEMAZEPAM	37	37		INSOMNIA		
Liebowitz	91005	54/Female	SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Liebowitz	91005	54/Female	MULTIVITAMINS	MULTIVITAMIN			Ongoing	SUPPLEMENT		
			IRON	IRON TAB	-7		Ongoing	DIETARY SUPPLEMENT		
			FOOD SUPPLEMENTS	WILD YAM	18		Ongoing	HORMONE SUPPLEMENT		
			HOMEOPATHIC MEDICINE	RED CLOVER	18		Ongoing	HORMONE SUPPLEMENT		
			GLUCOSAMINE SULPHATE	GLUCOSAMINE	18		Ongoing	JOINT PAIN		
			EXCEDRIN	EXCEDRIN	2		Ongoing	HEADACHE		
			VITAMIN B1 (THIAMINE HCL)	B-100 VITAMIN	0		Ongoing	DIETARY SUPPLEMENT		
			CHROMIUM PICOLINATE	CHROMIUM PICOLENATE	0		Ongoing	FAT BURNER		
			HOMEOPATHIC MEDICINE	ALGAE	0		Ongoing	DIETARY SUPPLEMENT		
	91006	44/Female	ADVIL	ADVIL	3		Ongoing	BACK PAIN		
			ASPIRIN (ACETYLSALICYLIC ACID,ASA)	ASPIRIN	4		Ongoing	HEADACHE		
			TYLENOL	TYLENOL	4		Ongoing	HEADACHE		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Liebowitz	91006	44/Female	TYLENOL MAXIMUM STRENGTH SINUS	TYLENOL SINUS			Ongoing	HEADACHE/SINUS	PATIENT HAS BEEN TAKING TYLENOL SINUS & MULTIVITAMI-NS PRIOR TO START OF STUDY MEDICATION - DATES UNKNOWN; CONTINUED AFTER END OF STUDY (LINES 1&10)	
			MIDOL	MIDOL	55	55		DYSMENORRHEA	PATIENT HAS BEEN TAKING TYLENOL SINUS & MULTIVITAMI-NS PRIOR TO START OF STUDY MEDICATION - DATES UNKNOWN; CONTINUED AFTER END OF STUDY (LINES 1&10)	
			PERCOCET	PERCOCET	16	16		MIGRAINE/HEADA-CHE	PATIENT HAS BEEN TAKING TYLENOL SINUS & MULTIVITAMI-NS PRIOR TO START OF STUDY MEDICATION - DATES UNKNOWN; CONTINUED AFTER END OF STUDY (LINES 1&10)	
			MULTIVITAMINS	MULTIVITAMINS			Ongoing	GOOD HEALTH	PATIENT HAS BEEN TAKING TYLENOL SINUS & MULTIVITAMI-NS PRIOR TO START OF STUDY MEDICATION - DATES UNKNOWN; CONTINUED AFTER END OF STUDY (LINES 1&10)	
	91097	38/Female	SYNTHROID	SYNTHROID				HYPOTHYROIDISM		
			CLARITIN	CLARITIN				ALLERGIES		

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Liebowitz	91097	38/Female	PREMSYN PMS	PREMYSEN PMS	14	14		PREMENSTRUAL SYNDROME		
			TYLENOL	TYLENOL	13	14		PMS HEADACHE		
			EX-LAX	EX-LAX REG. STRENGTH LAXATI-VE			Ongoing	CONSTIPATION		
			METROGEL VAGINAL	METRAGEL VAGINAL ANTIBIOTIC	21	35		UTI		
			ANACIN	ANACIN	27		Ongoing	BILATERAL CARP-EL TUNNEL		
			VALTREX	VALTREX	35	42		GENITAL HERPES		
			BACTRIM	BACTRIM	35	42		UTI		
	91137	40/Male	THERAFLU FLU & COLD MEDICINE	THERAFLU	2	11		FLU SYMPTOMS		
			ADVIL	ADVIL	19	19		HEADACHE		
					24	28		HEADACHE		
					29	30		HEADACHE		
					35	41		HEADACHE		
					42	49		HEADACHE		

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Liebowitz	91137	40/Male	ADVIL	ADVIL (IBUPROFE-N)	54	56		HEADACHE		
	91138	45/Female	AMBIEN	ZOLPIDEM (AMBIE-N)	28		Ongoing	INITIAL INSOMN-IA		
Londborg	101010	51/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN			Ongoing	CARDIAC PROPHY-LAXIS		
			IBUPROFEN	IBUPROFEN			Ongoing	ACHES & PAINS		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	9	9		HEADACHE		
			MOTRIN TABLETS	MOTRIN	37	38		BACK PAIN		
	101043	31/Female	AUGMENTIN	AUGMENTIN	28	37		SINUS INFECTION		
	101044	41/Female	IBUPROFEN	IBUPROFEN			Ongoing	DYSMENORRHEA		
			TEMAZEPAM	TEMAZEPAM	0	4		INSOMNIA		
					7		Ongoing	INSOMNIA		
			ORTHO-NOVUM	ORTHONOVUM 1/35			Ongoing	BIRTH CONTROL/ DYSMENORRHEA		
			IBUPROFEN	IBUPROFEN	33	33		TOOTHACHE		
			SUDAFED	SUDAFED	36	36		NASAL CONGESTI-ON		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Londborg	101044	41/Female	IBUPROFEN	IBUPROFEN	48	53		HEADACHE		
			NYQUIL LIQUICAPS	NYQUIL	115	141		COLD SYMPTOMS		
			MELATONIN	MELATONIN	145	157		INSOMNIA		
			DRAMAMINE II/ MECLIZINE W/ LACTOSE	DRAMAMINE II	146	167		INSOMNIA		
			NYQUIL LIQUICAPS	NYQUIL	171	174		COLD SYMPTOMS		
			MONISTAT 7	MONISTAT 7	66	73		YEAST INFECTION		
			IBUPROFEN	IBUPROFEN	103	105		BACKACHE		
			SUDAFED	SUDAFED	107	114		CONGESTION		
			DIPHENHYDRAMINE	DIPHENHYDRAMINE	127	144		CONGESTION		
			CALCIUM	CALCIUM	170		Ongoing	DIETARY SUPPLE-MENT		
			MAGNESIUM	MAGNESIUM	170		Ongoing	DIETARY SUPPLE-MENT		
			ZINC	ZINC	170		Ongoing	DIETARY SUPPLE-MENT		
			CEPHALEXIN	CEPHALEXIN	199	213		URINARY TRACT INFECTION		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Lydiard	221033	44/Male	AMBIEN	AMBIEN				INSOMNIA		
	221034	40/Female	TEMAZEPAM	TEMAZEPAM	-8		Ongoing	INSOMNIA		
			ADVIL	ADVIL	-5	-4		HEADACHE		
			GOODY'S HEADACHE POWDERS	GOODY'S	15	16		HEADACHE		
			ADVIL	ADVIL	21	21		HEADACHE		
			GOODY'S HEADACHE POWDERS	GOODY'S	22	22		HEADACHE		
			ALEVE	ALEVE	24	24		HEADACHE		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	28	28		HEADACHE		
			GOODY'S HEADACHE POWDERS	GOODY'S	29	29		HEADACHE		
			EX-LAX	EX LAX	38	38		CONSTIPATION		
			GOODY'S HEADACHE	GOODY'S	36	36		HEADACHE		
			POWDERS		40	40		HEADACHE		
	221130	51/Female	TEMAZEPAM	TEMAZEPAM	-20		Ongoing	INSOMNIA		
				METHOXYPROGESTE-RONE			Ongoing	HORMONE REPLAC-EMENT		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Lydiard	221130	51/Female	ESTROGEN	ESTERIFIED ESTROGEN			Ongoing	HORMONE REPLAC-EMENT		
				METHYLTESTERONE			Ongoing	HORMONE REPLAC-EMENT		
			ALEVE	ALEVE			Ongoing	HEADACHE		
			EXCEDRIN	EXCEDRINE	4	4		HEADACHE		
McGrath	111057	48/Male	TYLENOL	TYLENOL	3	4		HEADACHE		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	5	5		HEADACHE		
			TYLENOL	TYLENOL	8	9		HEADACHE		
			BETHANECHOL CHLORIDE	BETHANECHOL	12		Ongoing	URINARY RETENT-ION		
			TYLENOL	TYLENOL	13	13		HEADACHE		
					15	15		HEADACHE		
					17	17		HEADACHE		
			BETHANECHOL CHLORIDE	BETHANECOL	12	19		URINARY HESITA-NCY		
	111171	50/Male	NORVASC	NORVASC	-46		Ongoing	HTN		
			INDAPAMIDE	INDAPAMIDE	-46		Ongoing	HTN		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Moreines	121007	33/Female	TYLENOL EXTRA STRENGTH	TYLENOL EXTRA STRENGTH			Ongoing	HEADACHES		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN			Ongoing	HEADACHES		
			MACROBID	MACROBID	58	62		URINARY TRACT INFECTION		
			AMPICILLIN	AMPICILLIN	63	73		KIDNEY INFECTI-ON		
			BENADRYL SYSTEMIC	BENADRYL	70	70		ITCHING ON L ARM		
Munjack	131011	56/Male	LIPITOR	LIPITOR			Ongoing	HYPERCHOLESTER-OLEMIA		
			VITAMIN C	VITAMIN C			Ongoing	NUTRITIONAL SUPPLEMENT		
			CENTRUM	CENTRUM A-Z			Ongoing	NUTRITIONAL SUPPLEMENT		
			NASACORT	NASACORT	-16		Ongoing	SINUS CONGESTI-ON		
			TYLENOL	TYLENOL	2	2		HEADACHE		
			FLU(INFLUENZA) VACCINE	FLU SLOT	32	32		PROPHYLAXIS		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Munjack	131011	56/Male	ORUVAIL	ORAVAIL	80	82		"INFLAMED LIGA-MENT" MIDDLE FINGER - R HAND		
			SUDAFED	SUDAFED	86	88		SINUS INFECTION		
					89	89		SINUS INFECTION		
					97	97		SINUS INFECTION		
			TYLENOL	TYLENOL	156	156		TRIGGER FINGER OPERATION		
			HYDROCODONE	HYDROCODONE	176	177		MYALGIA-BACK	12- PREPARATION REPORTED AS 5 MG CODEINE WITH 500MG ACETAMINOPHEN	
			CRANBERRY	CRANBERRY CONCE-NTRATE	176	177		MYALGIA-BACK	12- PREPARATION REPORTED AS 5 MG CODEINE WITH 500MG ACETAMINOPHEN	
			TYLENOL	TYLENOL	4	4		HEADACHE	12- PREPARATION REPORTED AS 5 MG CODEINE WITH 500MG ACETAMINOPHEN	
	131012	42/Female	EXCEDRIN	EXCEDRIN	3	3		HEADACHE		
			EXCEDRIN PM	EXCEDRIN PM	61	63		HEADACHE		
			ALKA SELTZER PLUS COLD TABLETS	ALKA SELTZER COLD PLUS	64	64		COLD SYMPTOMS		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Munjack	131012	42/Female	VICODIN	VICODIN	82	82		MIGRAINE		
			ALKA SELTZER PLUS COLD TABLETS	ALKA SELTZER COLD PLUS	78	78		COLD SYMPTOMS		
	131072	58/Male	VENTOLIN/SALBUTAM-OL SULPHATE	VENTOLIN			Ongoing	ASTHMA BRONCHI-OLE		
				ALBUTEROL-VANCE-RIL			Ongoing	ASTHMA BRONCHI-ALE		
	131125	34/Female	TYLENOL EXTRA STRENGTH	TYLENOL EXTRA STRENGTH	19	19		HEADACHE		
			ADVIL	ADVIL	20	20		HEADACHE		
			PEPTO BISMOL	PEPTO BISMOL	21	22		HEARTBURN		
			NORVASC	NORVASAC			Ongoing	HYPERTENSION		
			SLOW FE	SLO FE NUTRITIO-NAL SUPPLEMENT			Ongoing	NUTRITIONAL SUPPLEMENT		
			ADVIL	ADVIL		19		HEADACHE		
			PEPTO BISMOL	PEPTO BISMOL	37	37		DIARRHEA		
			ADVIL	ADVIL	48	50		MENSTRUAL CRAM-PS		
					57	57		HEADACHE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Munjack	131125	34/Female	ADVIL	ADVIL	66	66		POST-OPERATIONAL PAIN (MAMMOTOMY)		
			LOCAL ANESTHETIC	LOCAL ANESTHETIC	65	65		MAMMOTOMY		
	131143	39/Female	MOTRIN TABLETS	MOTRIN	23	27		BACK PAIN AT (R) SCAPULA		
			IRON	IRON	0			ANEMIA PROFYLAXIS		
	131144	33/Female	PROVENTIL	PROVENTIL	10	11		ASTHMA BR. - EXACERBATION		
			ORTHO TRI CYCLEN	ORTHOBRYCYCLEN			Ongoing	BIRTH CONTROL		
			CLARITIN D/LORATADINE W/PSEUDOEPHEDRINE SULPHATE	CLARITIN D	-19	-4		ALLERGIES		
			IRON	IRON			Ongoing	NUTR. SUPPLEMENT		
			CALCIUM	CALCIUM			Ongoing	NUTR. SUPPLEMENT		
			VITAMIN B12 (CYANOCOBALAMIN CRYSTALLINE, HYDROXOCOBALAMIN)	VITAMIN B12			Ongoing	NUTRITIONAL SUPPLEMENT		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Munjack	131144	33/Female	MULTIVITAMINS	MULTI-VITAMINS			Ongoing	NUTR. SUPPLEME-NT		
			KEFLEX	KEFLEX	55	61		SPIDER BITE		
Nelson	141041	55/Female	ZOCOR	ZOCOR			Ongoing	HYPERCHOLESTER-OLEMIA		
			DETROL (DETRUSITO-L)/TOLTERODINE	DETROL			Ongoing	URINARY INCONT-INENCE		
			PREMPRO	PREM PRO			Ongoing	ESTROGEN REPLA-CEMENT		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN			Ongoing	PREVENT STROKE		
			ADALAT	ADOLAT			Ongoing	HYPERTENSION		
			EXCEDRIN	EXCEDRIN	13	14		HEADACHE		
			TYLENOL	TYLENOL	12	14		HEADACHE		
			EXCEDRIN	EXCEDRIN	16	16	Ongoing	HEADACHE		
					23		Ongoing	HEADACHE		
			TYLENOL	TYLENOL	23		Ongoing	HEADACHE		
			PROZAC	PROZAC	-28	-1		MINOR DEPRESSI-ON		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Nelson	141041	55/Female	SULFAMETHOXAZOLE	SULFAMETHOXAZOLE	39	47		UNINAY TRACT INFECTION		
			CITRACAL	CITRICAL			Ongoing	CALCIUM SUPPLE-MENT		
			FLU(INFLUENZA) VACCINE	FLUE VACCINE	36	36		FLUE PREVENTION		
Oldroyd	321055	38/Male	MYLANTA	MYLANTA			Ongoing	GASTROINTESTIN-AL REFLUX DISO-RDER		
			EXTRA STRENGTH TYLENOL PM	TYLENOL PM	15	15		INSOMNIA		
			VIVARIN	VIVARIN	17	17		ANERGIA		
	321056	44/Male	SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM	002: PROZAC WAS RESTARTED BY PATIENT ON HIS OWN AFTER STOPPING REBOXETINE	
			PROZAC	PROZAC	8		Ongoing	DEPRESSION	002: PROZAC WAS RESTARTED BY PATIENT ON HIS OWN AFTER STOPPING REBOXETINE	
	321087	55/Male	PILOCARPINE HCL	PILOCARPINE HYDROCHLORIDE 1%		43		GLAUCOMA		
			NAPROXEN	NAPROXEN	-108		Ongoing	ARTHRITIS LEFT HIP & LEFT SHOULDER		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Oldroyd	321087	55/Male	ZANTAC	ZANTAC	16		Ongoing	INDIGESTION		
			DIAMOX	DIAMOX	56	56		PUPIL DILATION	INSOMNIA IS SYMPTOM OF PRIMARY DEPRESSIVE DISORDER, NOT A CURRENT ADVERSE EVENT.	
			PILOCARPINE HCL	PILOCARPINE HYDROCHLORIDE 1%	56		Ongoing	GLAUCOMA	INSOMNIA IS SYMPTOM OF PRIMARY DEPRESSIVE DISORDER, NOT A CURRENT ADVERSE EVENT.	
			RESTORIL	RESTORIL	64	81		INSOMNIA	INSOMNIA IS SYMPTOM OF PRIMARY DEPRESSIVE DISORDER, NOT A CURRENT ADVERSE EVENT.	
Prover	261023	33/Female	PROVENTIL	PROVENTIL	-2E3			ASTHMA	#3 PT REPORTED SHE TOOK ASPIRIN AFTER A HIGH-FAT CONTENT MEAL FOR PROPHYLACT-IC REASONS	PATIENT DID NOT RETURN FOR FINAL VISIT UNABLE TO CONFIRM #1 END DATE.
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	8	8		BACKACHE	#3 PT REPORTED SHE TOOK ASPIRIN AFTER A HIGH-FAT CONTENT MEAL FOR PROPHYLACT-IC REASONS	PATIENT DID NOT RETURN FOR FINAL VISIT UNABLE TO CONFIRM #1 END DATE.
					18	18		PROPHYLAXIS	#3 PT REPORTED SHE TOOK ASPIRIN AFTER A HIGH-FAT CONTENT MEAL FOR PROPHYLACT-IC REASONS	PATIENT DID NOT RETURN FOR FINAL VISIT UNABLE TO CONFIRM #1 END DATE.

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Prover	261023	33/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	25	25		HEADACHE	PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO CONFIRM END DATE FOR #7.	
			ALBUTEROL SULFATE	ALBUTEROL	26	26		ALLERGY	PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO CONFIRM END DATE FOR #7.	
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	27	27		HEADACHE	PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO CONFIRM END DATE FOR #7.	
					41		Ongoing	HEADACHE	PATIENT DID NOT RETURN FOR FINAL VISIT. UNABLE TO CONFIRM END DATE FOR #7.	
			SEPTRA DS	SEPTRA DS	43	51		URINARY TRACT INFECTION		
			BACTRIM DS	BACTRIM DS	61	70		URINARY TRACT INFECTION		
			CIPRO	CIPRO	83	90		URINARY TRACT INFECTION		
			RESTORIL	RESTORIL	94	94		INSOMNIA		
			VITAMIN C	VITAMIN C	97	97		SORE THROAT	PT DID NOT RETURN FOR FINAL VISIT - UNABLE TO DETERMINE ACCURATELY IF CON MED IS ONGOING	

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Prover	261023	33/Female	RESTORIL	RESTORIL	100		Ongoing	INSOMNIA	PT DID NOT RETURN FOR FINAL VISIT - UNABLE TO DETERMINE ACCURATELY IF CON MED IS ONGOING	
Rapaport	151037	62/Female	TRIAMTERENE	TRIAMTERENE			Ongoing	HIGH BLOOD PRESSURE		
			ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT		
			IBUPROFEN	IBUPROFEN	-4	-4		ARTHRITIS IN KNEE		
			TAGAMET	TAGAMENT	3	3		GALL BALDDER INFECTION		
			DEMEROL	DEMEROL	3	3		GALL BLADDER INFECTION		
			SODIUM CHLORIDE (NORMAL SALINE, ISOTONIC,0.9%, NACL)	NS (SALINE)	3	3		GALL BLADDER INFECTION		
			SULINDAC	SULINDAC	3	3		GALL BLADDER INFECTION		
			DONNATAL	DONNATAL	3	3		GALL BLADDER INFECTION		
			ANTACID MEDICATION	ANTACID	28	29		STOMACH ACHE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151037	62/Female	IBUPROFEN	IBUPROFEN	61	73		NECK PAIN		
			TYLENOL	TYLENOL	65	65		NECK PAIN		
			ALEVE	ALEVE	71	71		HEADACHE		
			CYCLOBENZAPRINE	CYCLOBENZAPRINE	72	74		NECK PAIN		
			NAPROXEN	NAPROXEN	72		Ongoing	NECK PAIN		
			AUGMENTIN	AUGMENTIN	83	93		SINUS INFECTION		
			GUAIFENESIN	GUAIFENESIN	84	93		SINUS INFECTION		
			ATENOLOL	ATENOLOL	94		Ongoing	HIGH BLOOD PRESSURE		
			FLONASE	FLONASE	94		Ongoing	NASAL DECONGES-TION		
			IBUPROFEN	IBUPROFEN	103		Ongoing	KNEE PROBLEMS		
	151038	52/Male	ZANTAC	ZANTAC			Ongoing	STOMACH BLOATI-NG		
			REGLAN	REGLAN			Ongoing	STOMACH BLOATI-NG		
			ZOCOR	ZOCAR			Ongoing	HIGH CHOLESTER-OL		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151038	52/Male	PROTOSTAT	PERIOSTAT			Ongoing	DENTAL BONE LOSS		
			IBUPROFEN	IBUPROFEN	-3		Ongoing	ARTHRITIS		
			TYLENOL	TYLENOL	28	28		HEADACHE		
			FENTANYL	FENTANYL	29	29		BIOPSY		
			VERSED	VERSED	29	29		BIOPSY		
			CIPROFLOXACIN	CIPROFLOXACIN	29	31		INFECTION		
			TYLENOL	TYLENOL	49		Ongoing	BACK PAIN		
			CEPHALEXIN	CEPHALEXIN	53		Ongoing	RASH (HIP)		
			TYLENOL	TYLENOL (COLD)	74		Ongoing	COLD		
			DICLOXACILLIN	DICLOXACILLAN	77	81		RASH (HIP)		
	151085	50/Female	ALEVE	ALEVE	-2	-2		MUSCLE ACHE		
			TYLENOL	TYLENOL	11	11		BACK PAIN		
			ALEVE	ALEVE	12	12		BACK PAIN		
	151086	45/Female	ZANTAC	ZANTAC			Ongoing	ACID REFLEX		
			PREMARIN	PREMARIN			Ongoing	HORMONE REPLAC-EMENT		

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Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151086	45/Female	PROGESTERONE	PROGESTERONE			Ongoing	HORMONE REPLAC-EMENT		
			IMITREX/SUMATRIPT-AN	IMITREX			Ongoing	MIGRAINES		
			EXTRA STRENGTH TYLENOL PM	TYLENOL PM			Ongoing	SLEEP		
			IBUPROFEN	IBUPROFEN	-7	-6		CRAMPS		
			EXCEDRIN	EXCEDRIN	-1	-1		HEADACHES		
			DULCOLAX	DULCOLAX	5		Ongoing	CONSTIPATION		
			EXCEDRIN	EXCEDRIN	14		Ongoing	MIGRAINES		
			DYAZIDE	DYAZIDE	34		Ongoing	CONSTIPATION		
	151095	49/Male	SINUS MEDICATION	EQUATE	-3		Ongoing	SINUS/ALLERGY		
			IBUPROFEN	IBUPROFEN	-3		Ongoing	KNEE PROBLEMS		
			PEPCID AC	PEPCID-AC	-2		Ongoing	STOMACH GAS		
			DARVOCET-N	DARVASET	35	35		HEADACHES		
			ROBITUSSIN	ROBITUSSIN	49	51		FLU		
			ALKA SELTZER	ALKA SELTZER	48	50		FLU		
			NYQUIL LIQUICAPS	NYQUIL	49	50		FLU		

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151095	49/Male	NAPROSYN	NAPROSIN	72	72		HEADACHES		
	151096	60/Male	TIMOLOL MALEATE	TIMOLOL			Ongoing	GLAUCOMA		
			TRUSOPT	TRUSOPT			Ongoing	GLAUCOMA		
			XALATAN	XALATAN			Ongoing	GLAUCOMA		
			IBUPROFEN	IBUPROFEN	3	3		STIFF NECK		
			IMODIUM	IMMODIUM	14	14		DIARRHEA		
			PEPTO BISMOL	PEPTO BISMAL	14	14		DIARRHEA		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	17	17		ORTHOSTATIC HYPOTENSION		
			IBUPROFEN	IBUPROFEN	51	51		HEADACHES		
					43	43		BACK PAIN (PER HISTORY)		
	151099	52/Female	IMITREX/SUMATRIPT-AN	IMITREX			Ongoing	MIGRAINES		
								MIGRAINES		
			PROVERA	PROVERA			Ongoing	HORMONE REPLAC-EMENT		
			ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT		

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All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151099	52/Female	ADVIL	ADVIL	7	7		NECKPAIN		
			SEPTRA	SEPTRA	22	25		BLADDER INFECTION		
			TINACTIN	TINACTIN	24	24		COLD SORE		
			TAVIST	TAVIST	30	30		UPPER RESPIRATORY INFECTION		
			TYLENOL COLD MEDICATION	TYLENOL-COLD	29	29		UPPER RESPIRATORY INFECTION		
			EXCEDRIN	EXCEDRIN (MIGRAINE)	0		Ongoing	MIGRAINES (PER HISTORY)		
	151100	42/Female	ESTRACE	ESTRACE			Ongoing	HORMONE REPLACEMENT		
			LIPITOR	LIPITOR			Ongoing	CHOLESTEROL		
			BENADRYL SYSTEMIC	BENADRYL	0	0		COLD		
			IMIPRAMINE HCL	IMIPRIMINE	36		Ongoing	INSOMNIA	PT. STARTED IMIPRIMINE WITHOUT NOTIFYING SITE	
			SINUS MEDICATION	EQUATE	30		Ongoing	INSOMNIA	PT. STARTED IMIPRIMINE WITHOUT NOTIFYING SITE	
	151117	49/Female	LOESTRIN 21	LOESTRIN			Ongoing	BIRTH CONTROL		
			ADVIL	ADVIL	3	10		BRUISED HIP		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

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Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Rapaport	151117	49/Female	TYLENOL	TYLENOL	10	10		KNEE PAIN		
	151118	47/Male	SUDAFED	SUDAFED	-2		Ongoing	HEADACHES		
			IBUPROFEN	IBUPROFEN			Ongoing	HEADACHES		
			ALEVE	ALEVE	26	26		HEADACHES		
	151153	44/Male	DARVOCET-N	DARVOCET	-6		Ongoing	TOOTH PAIN		
			TRIMOX	TRIMOX	-4		Ongoing	TOOTH PAIN		
			IBUPROFEN	IBUPROFEN	-4		Ongoing	TOOTH PAIN		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	7		Ongoing	HEADACHES		
Smith	281026	46/Female	IBUPROFEN	IBUPROFEN			Ongoing	BACK PAIN		
			LORTAB	LORTAB	11		Ongoing	BACK PAIN		
	281101	40/Female	IBUPROFEN	IBUPROFEN			Ongoing	BACKACHE		
			ZYDONE	ZYDONE	-8	-7		BACKACHE		
			AMBIEN	AMBIEN	29		Ongoing	INSOMNIA		
	281102	44/Female	SINEMET-10/100	SINEMET			Ongoing	LEG SPASMS		
			MEDROXYPROGESTERO-NE ACETATE	MEDROXYPROGESTE-RONE ACETATE			Ongoing	IRREGULER MENS-TRATION		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Smith	281102	44/Female	CIPRO	CIPRO	6	10		BLADDER INFECT-ION		
			TYLENOL	TYLENOL	15	35		LEFT GREAT TOE PAIN		
			IBUPROFEN	IBUPROFEN	15	35		LEFT GREAT TOE PAIN		
			FIBERCON	FIBER-CON	32		Ongoing	CONSTIPATION		
	281107	61/Female	SYNTHROID	SYNTHROID			Ongoing	HYPOTHYROIDISM		
			ESTRACE	ESTRACE			Ongoing	HORMONE REPLAC-EMENT		
			PROPULSID	PROPULCID			Ongoing	ACID REFLUX		
			PRILOSEC (LOSEC)	PRILOSEC			Ongoing	ACID REFLUX		
			AMBIEN	AMBIEN	-14	10		INSOMNIA		
			MAXZIDE	MAXZIDE	3		Ongoing	BLOATING		
			ALEVE	ALEVE	1		Ongoing	HEADACHE		
			TYLENOL	TYLENOL	3		Ongoing	HEADACHE		
			AMBIEN	AMBIEN	11	17		INSOMNIA		
			TEMAZEPAM	TEMAZEPAM	18	28		INSOMNIA		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Smith	281107	61/Female	AMBIEN	AMBIEN	21		Ongoing	INSOMNIA		
			FIBERCON	FIBERCON	29		Ongoing	CONSTIPATION		
			VOLTAREN	VOLTAREN	31		Ongoing	HEADACHE		
			TEMAZEPAM	TEMAZEPAM	29		Ongoing	INSOMNIA		
	281108	53/Female	ATENOLOL	ATENOLOL			Ongoing	HYPERTENSION		
			AMBIEN	AMBIEN			Ongoing	INSOMNIA		
			K-DUR	K-DUR			Ongoing	PROPHYLAXIS HYPOKALEMIA		
			IBUPROFEN	IBUPROFEN	-9		Ongoing	BACK PAIN		
			ZITHROMAX	ZITHROMAX	18	23		SINUS INFECTION		
			GUAIFENESIN	GUAIFENESIN	18	29		BRONCHITIS		
			EXCEDRIN	EXCEDRIN	52		Ongoing	HEADACHE		
			VITAMIN E	VITAMIN E	-624		Ongoing	SUPPLEMENT		
			VITAMIN C	VITAMIN C	-624		Ongoing	SUPPLEMENT		
			CLIMARA	CLIMARA	-2E3		Ongoing	HORMONE REPLAC-EMENT		
			ADVIL	ADVIL	66		Ongoing	BODY ACHES		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Telew	171016	37/Male	PHILLIPS MILK OF MAGNESIA	PHILLIPS MILK OF MAGNESIA	3	3		CONSTIPATION		
					5	5		CONSTIPATION		
			TYLENOL	TYLENOL	26	26		MILD HEADACHE		
			TETANUS TOXOID	TETANUS SHOT	26	26		LACERATION TO LEG		
			DOAN'S PILLS	DOAN'S EXTRA STRENGTH	36	36		BACK ACHE		
			EXCEDRIN	EXCEDRIN MIGRAINE	40	40		HEADACHE		
			SUDAFED SINUS MAXIMUM STRENGTH	SUDAFED SINUS	46			SEASONAL ALLERGIES		
	171027	52/Female	ESTRADIOL ORAL	EXTRADIOL			Ongoing	HORMONE REPLACEMENT THERAPY		
			PROVERA	PROVERA			Ongoing	HORMONE REPLACEMENT THERAPY		
			PREVACID	PREVACID			Ongoing	ULCER		
			VICODIN	VICODIN			Ongoing	BACK PAIN		
			TAGAMET	TAGAMET			Ongoing	ULCER		
			AMBIEN	AMBIEN	1		Ongoing	INSOMNIA		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Telew	171027	52/Female	TYLENOL	TYLENOL	0		Ongoing	BACK PAIN		
			CELEBREX/CELECOXIB	CELEBREX	1		Ongoing	BACK PAIN		
			MIDRIN	MIDRIN	26	34		HEADACHE		
			SULFONAMIDE - SYSTEMIC	SULFA	20		Ongoing	DIETARY SUPPLE-MENT		
			PYRIDIUM	PYRIDIUM	20		Ongoing	UNK		
			CLARITIN	CLARITIN	23	23		HEADACHE		
			IBUPROFEN	IBUPROFEN	21	21		HEADACHE		
			CODEINE	CODEINE	18	18		HEADACHE		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	15	15		HEADACHE		
			ALKA SELTZER	ALKA-SELTZER	15		Ongoing	BODY ACHES		
			MICONAZOLE SYSTEM-IC	MICONAZOLE	9	12		YEAST INFECTION		
			XENICAL/ORLISTAT	XENICAL			Ongoing	WEIGHT CONTROL		
	171061	47/Female	DRIXORAL	DRIXORAL	-14		Ongoing	SEASONAL ALLER-GIES		
			ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	10	10		HEADACHE		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Telew	171061	47/Female	FLONASE	FLONASE	8		Ongoing	SEASONAL ALLERGIES		
			CLARITIN	CLARITIN	0		Ongoing	SEASONAL ALLERGIES		
			AMERGE/NARATRIPTAN HCL	AMERGE	16		Ongoing	MIGRAINE HEADACHE		
			RYNATAN	RYNATAN	24		Ongoing	VASOMOTOR RHINITIS		
			ASPIRIN (ACETYLSALICYLIC ACID,ASA)	ASPIRIN	16	16		HEADACHE		
Thase	181083	58/Male	VITAMIN C	VIT C			Ongoing	SUPPLEMENT		
			VITAMIN E	VIT E			Ongoing	SUPPLEMENT		
			VITAMIN B COMPLEX W/FOLIC ACID	B COMPLEX VIT W/ FOLIC ACID			Ongoing	SUPPLEMENT		
			VITAMIN A	VITAMIN A	-534		Ongoing	ACNE OUTBREAKS	006 FIRST REPORTED 1/28/00	
			HALL'S MENTHOLYPTUS COUGH TABLETS	HALLS MENTHOLYPTUS COUGH DROP	54	73		SORE THROAT	006 FIRST REPORTED 1/28/00	
			TUMS	TUMS	91	92		DYSPEPSIA	006 FIRST REPORTED 1/28/00	
			HOMEOPATHIC MEDICINE	FLAX SEED OIL	-685	134		STIFF JOINTS		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Thase	181084	32/Male	IBUPROFEN	IBUPROFEN	-382		Ongoing	PAIN		
			CLARITIN	CLARITIN	-535		Ongoing	ALLERGY		
			M.V.I.	MVI	-382		Ongoing	SUPPLEMENT		
			CALCIUM	CALCIUM	-109		Ongoing	SUPPLEMENT		
			TUSSIN	TUSSIN-CF COUGH SYRUP	32	34		COLD SYMPTOMS		
			NAPROXEN SODIUM	NAPROXEN SODIUM	35	35		SINUS HEADACHE		
					67		Ongoing	PAIN		
			CHLORPHENIRAMINE MALEATE(CHLORPHEN-AMINE)	CHLORPHENIRAMIDE MALEATE	9		Ongoing	ENVIRONMENTAL ALLERGY		
			HOMEOPATHIC MEDICINE	FLAX SEED OIL	-686	133		STIFF JOINTS		
	181105	37/Female	ORTHO TRI CYCLEN	ORTHO TRI-CYCLEN			Ongoing	DYSMENORRHEA		
			TUMS	TUMS	-65		Ongoing	CALCIUM SUPPLE-MENT		
			MULTIVITAMINS	MULTIPLE VITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		
			FLONASE	FLONASE		6		CHRONIC SINUSI-TIS		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Thase	181105	37/Female	METROGEL	METROGEL	-8		Ongoing	ACNE ROSACEA		
			TYLENOL ALLERGY SINUS NIGHT TIME, MAXIMUM STRENGTH	TYLENOL ALLERGY SINUS	14	14		SINUSITIS		
			VICKS DAYQUIL	DAYQUIL	17	20		UPPER RESPIRAT-ORY INFECTION		
			NYQUIL LIQUICAPS	NYQUIL	17	20		UPPER RESPIRAT-ORY INFECTION		
			BIAXIN	BIAXIN	22	33		UPPER RESPIRAT-ORY INFECTION		
			TUMS	TUMS	36	36		INDIGESTION		
			ALLEGRA-D	ALLEGRA-D	46	46		SINUSITIS		
	181106	28/Male	ACETAMINOPHEN(APA-P)	ACETIMINOPHEN			Ongoing	INTERMITTENT HEADACHES	001: PRN	
	181135	31/Female	NAPROXEN	NAPROXEN	1		Ongoing	MENSTRUAL CRAM-PS		
			PEPCID AC	PEPCID AC	25	25		HEARTBURN		
			GAVISCON	GAVISCON	26		Ongoing	HEARTBURN		
	181136	55/Female	TUMS	TUMS	-63		Ongoing	REFLUX		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Thase	181136	55/Female	PREMPRO	PREMPRO	-572		Ongoing	MENOPAUSAL SYMPTOMS		
			VITAMIN E	VITAMIN E			Ongoing	HEALTH MAINTEN-ANCE		
				LLYCINE	8	14		COLD SORES		
			MULTIVITAMINS	MULTIVITAMIN	29	50		GENERAL HEALTH		
			VITAMIN C	VITAMIN C	29	42		HEALTH MAINTEN-ANCE		
Trivedi	191013	36/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPRIN	-2	-2		HEADACHE		
			DESOGEN	DESOGIN		34		CONTRACEPTION		
			ALBUTEROL SULFATE	ALBUTEROL			Ongoing	ASTHMA		
			CLARITIN	CLARITIN-A			Ongoing	SEASONAL ALLER-GIES		
			MULTIVITAMINS	MULTIVITAMIN			Ongoing	NUTRITIONAL SUPPLEMENT		
			NUTRITIONAL SUPPLEMENT	POS. ENERGY NUTRITIONAL SUPP .			Ongoing	NUTRITIONAL SUPPLEMENT		
			ANTIOXIDANT	ANTIOXIDANT		-5		SUPPLEMENT		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Trivedi	191013	36/Female	MECLIZINE HCL (MECLOZINE HCL)	MECLIZINE HCL	-19		Ongoing	NAUSEA		
			IBUPROFEN	IBUPROFEN	6	11		HEADACHE		
			RHINOCORT	RHINOCORT	-395		Ongoing	SEASONAL ALLER-GIES		
			AMINO ACID (AS SOLUTION)(POLYPEP-TIDES-PARENTERAL)	AMINO ACID			Ongoing	NUTRITIONAL SUPPLEMENT		
			BEE POLLEN	BEE POLLEN			Ongoing	NUTRITIONAL SUPPLEMENT		
			ORTHO-CYCLEN	ORTHO-CYCLEN	41		Ongoing	CONTRACEPTIVE		
			DRUG, UNRECOGNIZA-BLE	UNKNOWN PMS PILLS			Ongoing	PMS		
	191014	47/Male	IBUPROFEN	IBUPROFEN	17	17		TOOTHACHE		
					18	21		TOOTHACHE		
			PENICILLIN VK	PENICILLIN VK	19	19		TOOTH ABCESS		
					20	27		TOOTH ABCESS		
			IBUPROFEN	IBUPROFEN	22	27		TOOTHACHE		
					23	26		TOOTHACHE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Trivedi	191014	47/Male	IBUPROFEN	IBUPROFEN	24	24		TOOTHACHE		
					34	34		HEADACHE		
					36	40		TOOTHACHE		
					37	40		TOOTHACHE		
			PENICILLIN VK	PENICILLIN VK	38	44		DENTAL WORK		
			IBUPROFEN	IBUPROFEN	68	68		HEADACHE		
					85		Ongoing	HEADACHE		
			ALCOHOL (ETOH)	ALCOHOLIC BEVERAGE	4	4		SOCIAL CONSUMPTION		
Walsh	171015	45/Female	ATENOLOL	ATENOLOL	-2E3		Ongoing	HYPERTENSION		
			IBUPROFEN	IBUPROFEN	14	14		HEADACHE		
			TRIAMTERENE	TRIAMTERENE	26	26		LEG EDEMA		
			ADVIL	ADVIL	29	29		HEADACHE		
			BENADRYL SYSTEMIC	BENADRYL	32	32		BEE STING		
					45	45		INSOMNIA		
			ADVIL	ADVIL	60	61		BACK ACHE		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Walsh	171015	45/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	-10	-10		HEADACHE		
			ADVIL	ADVIL	76	76		SORE SHOULDER		
	171027	52/Female	RESTORIL	RESTORIL			Ongoing	INSOMNIA	PATIENT REPORTED ON SELF COMPLETED CON MED HISTORY THAT SHE TAKES CON MED AT (PRESENT) OCCASSIONALY FOR HEADACHES. PATIENT DIDN'T REPORT TAKING DURING	STUDY
			PERCOCET	PERCOSET			Ongoing	HEADACHES	PATIENT REPORTED ON SELF COMPLETED CON MED HISTORY THAT SHE TAKES CON MED AT (PRESENT) OCCASSIONALY FOR HEADACHES. PATIENT DIDN'T REPORT TAKING DURING	STUDY
			SOMA	SOMA	30		Ongoing	DIETARY SUPPLE-MENT	PATIENT REPORTED ON SELF COMPLETED CON MED HISTORY THAT SHE TAKES CON MED AT (PRESENT) OCCASSIONALY FOR HEADACHES. PATIENT DIDN'T REPORT TAKING DURING	STUDY
	171028	45/Female	EXCEDRIN	EXCEDRIN	-3	-3		HEADACHE		
			ALEVE	ALLEVE	-2	-2		HEADACHE		
			EXCEDRIN	EXCEDRIN	9	9		HEADACHE		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Walsh	171028	45/Female	ASPIRIN (ACETYLSA-LICYLIC ACID,ASA)	ASPIRIN	15	15		HEADACHE		
			TAVIST-D	TAVIST-D	14	14		HEADAHCE		
			EXTRA STRENGTH TYLENOL PM	TYLENOL PM	15	15		INSOMNIA		
			TYLENOL ALLERGY SINUS NIGHT TIME, MAXIMUM STRENGTH	TYLENOL COLD AND SINUS	14	15		HEADACHE		
	171062	52/Female	TYLENOL	TYLENOL	7	7		BACKACHE		
			LACTOBACILLUS ACIDOPHILUS	ACIDOPHOLUS	6		Ongoing	HEARTBURN		
			TUMS	ANTACID - TUMS	44	48		INDIGESTION		
			TYLENOL	TYLENOL	52	58		VIRAL UPPER RESPIRATORY INFECTION		
	171063	27/Male	ACYCLOVIR SYSTEMIC	ACYCLOVIR	-139		Ongoing	ORAL HERPES		
			AMBIEN	AMBEIN	10		Ongoing	INSOMNIA		
			ADVIL	ADVIL	27	27		HEADACHE		
			TAGAMET	TAGAMENT	79		Ongoing	HEARTBURN		
			ADVIL	ADVIL	85	86		SHOULDER PAIN		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Walsh	171063	27/Male	ADVIL	ADVIL	79	79		SHOULDER PAIN		
			IBUPROFEN	IBUPROFEN	63	64		HEADACHE		
			ADVIL	ADVIL	58	60		NECKPAIN		
					56	56		NECKPAIN		
	171064	21/Female	ADVIL	ADVIL	3	4		HEADACHE		
			NECON/ORTHO-NOVUM	NECON	1		Ongoing	BIRTH CONTROL		
			VICODIN	VICODIN	13	14		LACERATION TO RIGHT KNEE		
			CEPHALEXIN	CEPHALEXIN	13	22		LACERATION TO RIGHT KNEE		
Zajecka	201067	31/Male	LAMISIL	LAMISAL		1		FUNGUS INFECTI-ON IN TOE		
					16	56		FUNGUS INFECTI-ON IN TOE		
	201068	37/Female	COZAAR/LOSARTAN POTASSIUM	COZAAR			Ongoing	HIGH BLOOD PRESSURE		
			TRI-NORINYL	TRI NORINYL			Ongoing	BIRTH CONTROL		
			DOCUSATE SODIUM W/ CASANTHRANOL	DOCUSATE SODIUM W/CASANTHRANOL	11	17		CONSTIPATION		

LIST10

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Zajecka	201068	37/Female	METAMUCIL	METAMUCIL	31	76		CONSTIPATION		
			ALLEGRA-D	ALLEGRA-D	34		Ongoing	SEASONAL ALLER-GIES		
	201091	34/Female	ORTHO NOVUM 7/7/7	ORTHONOVUM 7/7/7 /28			Ongoing	BIRHT CONTROL		
			CLARITIN	CLARITIN	-366		Ongoing	SEASONAL ALLER-GIES		
			ALBUTEROL SULFATE	ALBUTEROL INHAL-ER			Ongoing	ASTHMA		
			MULTIVITAMINS	MULTIVITAMIN			Ongoing	SUPPLEMENT		
			AZMACORT	AZMACORT			Ongoing	ASTHMA		
			MOTRIN TABLETS	MOTRIN	0		Ongoing	MUSCLE STRAIN		
			FELDENE	FELDENE	5		Ongoing	MUSCLE STRAIN		
			PROPOXYPHENE NAPSYLATE	PROPOXYPHENE NAPSYLATE	5		Ongoing	MUSCLE STRAIN	LINE #08: PT WAS EVENTLY NON-CONPLIANT IN HER USE OF THIS MEDICATION FOR MUSCLE STRAIN AFTER CLEAR WARNING THIS WOULD NOT BE ALLOWED IN STUDY.	
	201092	41/Female	RESTORIL	RESTORIL	7	8		INSOMNIA		
			METAMUCIL	METAMUCIL	8	23		CONSTIPATION		

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Concomitant Medication - Patient Listing
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Age/Sex	Therapeutic Class	Name on CRF	Start Day	Stop Day	Ongoing at Final Visit	Reason for Use	Comment	Additional Comment
Zajecka	201092	41/Female	MOTRIN TABLETS	MOTRIN	19	23		INTERMITTENT HEADACHE		
			KLONOPIN	KLONOPIN	23		Ongoing	DEPRESSION		
			WELLBUTRIN	WELLBUTRIN	24		Ongoing	DEPRESSION		
			ZOLOFT	ZOLOFT	26		Ongoing	DEPRESSION		
	201123	43/Female	MULTIVITAMINS	MULTIVITAMIN				PROPHYLAXIS		
			NAPROSYN	NAPROSIN				SINUSITIS		
			METAMUCIL	METAMUCIL	15			CONSTIPATION		

LIST11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Amsterdam	11065	Week 1	No	PATIENT DISCARDED DRUG VIAL #1
		Week 2	No	SITE NOR PT. CANNOT ACCOUNT FOR MISSING PILLS
		Week 3	No	CANNOT EXPLAIN MISSING PILLS
		Week 4	No	DID NOT RETURN VIAL
		Week 6	Yes	PT. MAY HAVE MISSED 3 DOSES IF HE DID NOT STILL HAVE EXTRAS THAT WERE UNRETURNED AT THIS POINT. WE ARE UNABLE TO DETERMINE HIS COMPLIANCE
	11066	Week 9	Yes	MEDICATION WAS NOT AVAILABLE
	11133	Week 3	Yes	PATIENT DID NOT TAKE MEDS ON 2/13 PM DOSE AND 2/14 MISSED A TOTAL OF 4 PILLS. ALSO MISSED AM DOSE ON 2/15/00
		Week 4	No	PATIENT FORGOT TO RETURN MEDS
	11134	Week 4	No	PILLS BROKEN IN PIECES
		Week 7	No	3/29/00-04/05/00 SUBJECT MISUNDERSTOOD DOSAGE AND TOOK 1.5 PILLS AT BOTH AM & PM INSTEAD OF EITHER/OR. SUBJECT WAS CORRECTED AT THIS VISIT.
	11160	Week 2	No	WILL RETURN STUDY DRUG AT NEXT VISIT (ONLY MISSED 1 PM PILL)

LIST11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Barbee	21053	Week 1	Yes	MISSEED 3/12 TO 3/14 DUE TO INTESTIONAL VIRUS (6 CONSECUTIVE DOSES)
Clayton	31111	Week 8	Yes	PT. STOPPED TAKING DRUG ON HER OWN
Croft	231002	Week 8	Yes	DUE TO AE PT FORGOT TO TAKE MEDICATION FROM 11/09 - 11/17/99
	231079	Week 5	No	PER PATIENT REPORT FORGOT BOTTLE AND DIARY WILL BRING AT NEXT APPOINTMENT. BOTTLE RETURNED 01/18/00
DuBoff	311017	Week 9	Yes	OFF DRUG FROM 12/20/99-12/22/99 SUBJECT RECEIVED MEDICATION THE MORNING OF 12/25/99 VIA FEDEX
	311115	Week 1	Yes	SUBJECT SKIPPED DOSES ON 12/18 & 12/19, 12/20 PER DR DUBOFF DUE TO AES
		Week 3	No	SUBJECT MISSED 2 DOSES ON 2000-01-01
		Week 5	No	SUBJECT MISSED ONE DOSE ON 1/15/00 AND ONE DOSE ON 1/16/00 IN ERROR
		Week 9	No	SUBJECT MISSED 2 DOSES ON UNKNOWN DATES
		Week 10	No	2/24/00 PM DOSE & 2/20/00 PM DOSE MISSED IN ERROR
		Week 11	No	SUBJECT MISSED PM DOSE ON 01MAR00
Dunner	211039	Week 1	No	DID NOT RETURN MED BOTTLE AT THIS VISIT, BUT PER PT REPORT TOOK MED AS PRESCRIBED.

LIST11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Dunner	211039	Week 2	No	RETURNED MEDS FROM BOTTLE 1 & 2
		Week 6	No	APPEARS PT MISSED 1.5 DOSE
	211040	Week 9	No	APPEARS MAY HAVE MISSED ONE DOSE
	211109	Week 3	No	PT STATES POSSIBLY MISSED ONE DOSE UNK DATE. LEFT MEDS AT HOME.
		Week 6	No	PT HAD MISSED VISIT 5 BUT MEDS WERE MAILED. RETURNS TOTAL OF 18 FROM TOTAL OF 50 DISPENSED SINCE 1/7/00 VISIT
		Week 8	No	PT HAD UNSCHED. VISIT ON 2/4 RETURNED 7.5 WAS DISP. 12.5 TO TAKE UNTIL TO SCHED. V8 FOR TODAY 2/8
		Week 32/Final	No	BY COUNT APPEARS PT. MAY HAVE TAKEN 1.5 MG. EXTRA
	211110	Week 4	No	PT. MISSED EVE.DOSE 2/8/00
		Week 10	No	COUNT INDICATES MAY HAVE MISSED 1/2 PILL
	211145	Week 8	No	MISSED ONE DOSE ON 3/21
	211146	Week 4	No	PT. DID NOT RETURN MEDICATION AT THIS VISIT. PT. RETURNED 11 ON 3/28/00
		Week 6	No	RETURNS 1/2 TAB EXTRA UNK REASON

LIST11

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Dunner	211146	Week 7	No	APPEARS MISSED 1 DOSE OF 1 1/2 TAB
	211147	Week 8		DRUG CONFISCATED DURING HOSPITAL STAY
Fava	51114	Week 5	No	PATIENT RECORDED OF DOSE INCREASE
	51141	Week 2	No	"20" THIS INCLUDED TABLETS FROM WK 1 & WK 2 BOTTLES AS KEG-HAD FINISHED WK 1 BOTTLE BEFORE USING WK 2 BOTTLE.
		Week 3	No	DRUG SENT VIA UPS TO PATIENT
		Week 4		UNK, PHONE VISIT, PATIENT WILL RETURN NEXT WEEK
		Week 5	No	PATIENT RETURNED 3 BOTTLES TODAY AND HAD NOT OPENED ONE
Ferguson	241031	Week 8	Yes	EARLY TERMINATED
Gilmer	61081	Week 8	Yes	AE'S
Helfing	81075	Week 4	No	PT MISSED A DOSE PER ACCOUNTABILITY BUT PT'S DIARY INDICATES ALL DOSES WERE TAKEN (DIDN'T MISS DOSE)
		Week 20	No	PT. REPORTED DISCARDING WEEK 17,WEEK 18,AND WEEK 19 BOTTLES AS THEY WERE EMPTY, CANNOT VERIFY DRUG ACCOUNTABILITY FOR THOSE WEEKS

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Helfing	81076	Week 5	No	MISSING ONE TABLET
		Week 7	No	PT. MISSED 1 DOSE
		Week 11	Yes	PATIENT MISSED 2.5 DOSES. WENT OUT OF TOWN AND FORGOT MEDS.
		Week 14	No	PT MISSED 1 DOSE
		Week 15	No	PATIENT MISSED 1 DOSE
		Week 32/Final	Yes	PER DRUG RETURN AND INCOMPLETE DIARY PT APPEARS TO HAVE MISSED MANY DOSES UNABLE TO VERIFY DRUG ACCOUNTABLITY PER INCOMPLETE DIARY
	81103	Week 2	No	PT TRIED TAKING 0.5 TABLET FOR 1 DOSE; PT WAS COUNSELED AT VISIT AGAINST DOING THIS IN FUTURE.
Hoopes	271045	Week 4	Yes	PT STATES HE FORGOT - PATIENT RETURNED MEDICATION 10/29/99
Liebowitz	91005	Week 8	No	PT REDUCED DOSAGE BACK TO 8MG QD ON 7/17/99 PER INVESTIGATOR REQUEST
	91006	Week 2	Yes	MISSED 3 DOSES ONLY REMEMBERS MISSING 1 DOSE
		Week 4	No	PATIENT LOST 2 PILLS
	91098	Week 8	Yes	PATIENT DISCONTINUED FROM STUDY

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Londborg	101044	Week 6	No	LOST 1 PILL DOWN DRAIN
		Week 10	No	PATIENT RETURNED EXTRA .5 TAB, PATIENT REPORTS POSSIBLY TAKING ON 8 MG ON ONE DAY INSTEAD OF PRESCRIBED 10MG
		Week 12	No	EXTRA .5 TAB RETURNED PATIENT POSSIBLY TOOK ONLY 8MG ON ONE DAY VS. 10 MG UNABLE TO ASCERTAIN WHICH DAY
McGrath	111057	Week 1	Yes	PT IS HAVING SIDE EFFECTS, CALLED DR. MCGRATH ON 11/15/99 WHO ADVISED HIM TO CUT BACK DOSE
		Week 8	Yes	TOOK PILLS EVERY OTHER DAY DUE TO INCREASING AE'S
	111058	Week 1	No	PT FORGOT MEDS - REMINDED TO RETURN NEXT VISIT. 3/22/00- PT RETURNED MEDS- #11.
		Week 3	No	PM DOSE 3/25 HELD SECONDARY CONSTIPATION
	111171	Week 7	No	STUDY MEDS BOTTLE REISSUED FOR PT. TO TAPER.
		Week 8	No	STUDY MEDS BOTTLE REISSUED FOR PT. TO TAPER
Moreines	121007	Week 2	No	PT FORGOT TO BRING IN BOTTLE OF PILLS-WILL BRING IN ON NEXT VISIT. ADDENDUM - ON 8/9/99 PT RETURNED BOTTLE FROM WEEK 2 FOR A TOTAL OF 9 TABLETS
		Week 3	Yes	DUE TO ILLNESS (FOOD POISONING)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Moreines	121007	Week 9	Yes	PT MISSED 6 DOSES
		Week 11	Yes	WAS AWAY FROM HOME ON 9/26/99 THEREFORE MISSED DOSES
		Week 32/Final	Yes	MISSED 4 DOSES - 2 ON 10/7/99, 1 ON 10/11/99 AND 1 ON 10/8/99
Munjack	131012	Week 24	No	5 TABLETS LAST FROM WEEK 23 BOTTLE
	131071	Week 1	No	WEEK 1 MEDS NOT RETURNED TODAY
	131143	Week 6	No	1/2 TAB LOST BY PT
		Week 7	No	PT RETURNED 1 TAB EXTRA - PT STATED THEY DID NOT MISS A SINGLE DOSE
Oldroyd	321055	Week 2	No	DID NOT RETURN WK2 BOTTLE IN ERROR.WILL RETURN AT WK3.COUNSELLED DENIES MISSING ANY DOSES.
	321087	Week 12	No	MISSED DOSE 1/17/00 IN ERROR
Rapaport	151037	Week 3	No	PT. MISSED DOSE 8/5/99 PM
		Week 11	Yes	PATIENT WAS SICK WITH SINUS INFECTION
	151038	Week 32/Final	Yes	PT DISCONTINUED MEDS ON 2/6/00.
	151096	Week 3	Yes	PT MISSED 3 DOSES ON 11/27/99 & 11/28/99

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Rapaport	151153	Week 8	Yes	PATIENT MISSED AM DOSE ON 4/2/00 AND TOOK LAST DOSE IN PM ON 4/2/00
Telew	171015	Week 11	No	PATIENT SHOULD HAVE RETURNED 11.5 TABLETS PER DIARY. UNKNOWN IF EXTRA, 5 TABLET WAS TAKEN
	171016	Week 1	No	1 TABLET MISSING
		Week 4	No	MISSED 2 DOSES
		Week 7	No	PT MISSED TWO DOSES
	171027	Week 2	No	PT. TOOK 1 EXTRA DOSE OR LOST TABLET OUTCOME UNKNOWN
		Week 3	No	SUBJECT MISSED 1 PM DOSE 8/13/99
		Week 8	Yes	SUBJECT CUT BACK DOSE DUE TO SIDE EFFECTS
Thase	181083	Week 3	No	PT HAS TAKEN SUB-LINGUALLY IN PAST WEEK. ADVISED TO STOP THAT, RETURN TO PO.
	181084	Week 7	No	MISS 1 1/2 TABS. LIKELY 12/31/99
		Week 11	No	1 PILL UNACCOUNTED FOR
		Week 13	No	HE MAY HAVE TAKEN 1 EXTRA DOSE IN ERROR
		Week 16	No	MISS 1 PILL ON 3/4/00

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Thase	181105	Week 4	Yes	BELIEVED 2 DAY WORSENING OF DEPRESSIVE SYMPTOMS WERE DUE TO REBOXETINE
		Week 5	No	3.5 TABS UNACCOUNTED,PT RELATES PROBLEM WITH SPLITTER AND WASTE OF TABS
	181106	Week 1	No	BOTTLE BROUGHT BACK 3/3/00
	181135	Week 8	Yes	PT STOPPED TAKING MEDS ON 4/7/00
	181136	Week 2	Yes	MISSED DUE TO WORK SCHEDULE. PT COUNSELLED WEEK 1 BOTTLE WITH 12 TABLETS & WEEK 2 BOTTLE WITH 15 TABLETS
Trivedi	191013	Week 2	Yes	PT WAS TAKING MEDS INCORRECTLY, 1 TAB/DAY
Walsh	171015	Week 1	No	PT STARTED MEDICATION ON 7/2/99 RATHER THAN 7/1/99 DUE TO PT CONFUSION.
		Week 5	No	PT MISSED 1 DOSE ON 7/27/99 PM
		Week 6	No	PT MISSED ONE DOSE ON 8/7/99
		Week 7	No	PER DIARY PT MISSED BID DOSE 8/15/99.PT REPORTS MISSING ONE DOSE.8.5 TABS RETURNED INDICATES PT TOOK PM DOSE 3/15/99 BUT IS UNKNOWN AT THIS TIME.
		Week 8	No	PT SHOULD HAVE RETURNED 8.5, PATIENT MISSED 5 DOSES

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Walsh	171015	Week 10	Yes	PATIENT SHOULD HAVE RETURNED 4 TABS PER DIARY 21 TABS TAKEN. UNKNOWN IF MEDICATION WAS MISSED OR TOO MANY IN BOTTLE ORIGINALLY
		Week 32/Final	No	PATIENT SHOULD HAVE RETURNED 10 TABLETS. UNKNOWN IF PATIENT TOOK 1.5 TABLETS EXTRA.
	171028	Week 1	No	PT. MISSED ONE DOSE
	171061	Week 1	No	PT MISSED 2 DOSES OF MEDS
		Week 2	No	PT MISSED ONE DOSE
		Week 8	Yes	PT MISSED 3 DOSES OF DRUG
	171062	Week 1	No	PT SHOULD HAVE RETURNED 11, TOOK ONE EXTRA DOSE
		Week 4	No	PT LOST 2 DOSE
		Week 6	No	PATIENT MAY HAVE TAKEN ONE EXTRA DOSE DOES NOT KNOW
		Week 7	No	PATIENT MISSING ONE DOSE DOESN'T RECALL IF SHE TOOK IT OR NOT
		Week 8	No	PATIENT MISPLACED TWO DOSE OF MEDS
	171063	Week 1	No	PATIENT MISSED AN DOSE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Study Medication Record: Comments on Whether Patient Skipped Drug For More Than Two Doses Per Week
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Skipped More Than 2 Doses (Yes/No)	Comments
Walsh	171063	Week 4	No	PATIENT MISSED ONE DOSE
	171064	Week 1	No	PT MISSED ONE DOSE
Zajecka	201067	Week 32/Final	Yes	MEDICATION RETURN ON 3/3/00
	201068	Week 1	No	PT STARTED MEDS ON 10-23-99 DUE TO HER SCHEDULE
		Week 32/Final	Yes	TERMINATED ON 1-28-00, FINAL VISIT TODAY 2-4-00
	201092	Week 2	Yes	PATIENT LEFT BOTTLE IN CAROLINA, MISSED 3 DOSES. TO RETURN BOTTLE 2 AT NEXT VISIT. PATIENT RETURNED ON 3/14/00
		Week 3	No	PER DIARY PATIENT TOOK 14 BUT COUNT SHOWS 12 TAKEN UNKNOWN, MISSED DOSES

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31019	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31020	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31047	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31047	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31019	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	31020	Week 4	MCSOD: MUCOUS THREADS FEW
	31019	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31019	Week 8	RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *
			RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
	31047	Week 4	MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	31019	Week 32/Final	MCSOD: AMORPHOUS SEDIMENT FEW
		visit	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31020	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31020	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31047	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31047	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	31048	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 4	MCSOD: BACTERIA OCCASIONAL

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31048	Week 4	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31048	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	31112	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31112	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31112	Week 8	PGTST:PREGNANT FEMALES:
		Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	31111	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31111	Week 8	PGTST:PREGNANT FEMALES:
	31020	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	31111	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Clayton	31111	Screen	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Croft	231120	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			WBCUCG:VERIFIED BY REPEAT ANALYSIS
	231079	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231119	Screen	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231080	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231002	Screen	MCSOD: BACTERIA FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231002	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	231001	Screen	MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231001	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	231139	Week 4	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	231079	Unscheduled	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	231080	Week 4	MCSOD: BACTERIA OCCASIONAL
			MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231080	Week 4	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	231119	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	231079	Week 4	MCSOD: AMORPHOUS SEDIMENT NO SPECIMEN RECEIVED
			MCSOD: AMMONIUM URATES NO SPECIMEN RECEIVED
			MCSOD: BACTERIA NO SPECIMEN RECEIVED
			MCSOD: COARSE GRANULAR CAST NO SPECIMEN RECEIVED
			MCSOD: CALCIUM OXALATE CRYS NO SPECIMEN RECEIVED
			MCSOD: FINE GRANULAR CASTS NO SPECIMEN RECEIVED
			MCSOD: FATTY CASTS NO SPECIMEN RECEIVED
			MCSOD: HYALINE CASTS NO SPECIMEN RECEIVED
			MCSOD: MUCOUS THREADS NO SPECIMEN RECEIVED
			MCSOD: RBC CASTS NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231079	Week 4	MCSOD: ROUND EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SQUAMOUS EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SULFA-LIKE CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: TRIPLE PHOSPH. CRYS NO SPECIMEN RECEIVED
			MCSOD: TRICHOMONAS NO SPECIMEN RECEIVED
			MCSOD: URIC ACID CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: WAXY CASTS NO SPECIMEN RECEIVED
			MCSOD: WBC CASTS NO SPECIMEN RECEIVED
			MCSOD: YEAST CELLS NO SPECIMEN RECEIVED
			CHRTG:NO SPECIMEN RECEIVED
			BILIUG:NO SPECIMEN RECEIVED
			UROBLG:NO SPECIMEN RECEIVED
			COLORG:NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231079	Week 4	GLCUG:NO SPECIMEN RECEIVED
			KETUG:NO SPECIMEN RECEIVED
			WBCUCG:NO SPECIMEN RECEIVED
			NITUG:NO SPECIMEN RECEIVED
			BLDUG:NO SPECIMEN RECEIVED
			PRTUG:NO SPECIMEN RECEIVED
			RBCUG:NO SPECIMEN RECEIVED
			RSUG:NO SPECIMEN RECEIVED
			WBCUG:NO SPECIMEN RECEIVED
			SPGRG:NO SPECIMEN RECEIVED
			PHUG:NO SPECIMEN RECEIVED
	231139	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231139	Week 8	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231001	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			GLUC:CELLS PROMPTLY. REFERENCE RANGES MAY
			GLUC:NOT APPLY TO THIS SPECIMEN; SUBMISSION
	231119	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231119	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231120	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231120	Week 8	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231079	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231080	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231080	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	231001	Week 32/Final visit	GLUC:NOT REFLECT PATIENT'S TRUE VALUE IF
			GLUC:OF ANOTHER SAMPLE IS RECOMMENDED.
			GLUC:RESULT IS ANALYTICALLY CORRECT BUT MAY
			GLUC:THE SERUM WAS NOT SEPARATED FROM THE
			GLUC:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231001	Week 32/Final visit	PGTST:PREGNANT FEMALES:
		Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	231002	Unscheduled	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231002	Unscheduled	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	231139	Screen	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231139	Screen	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	231120	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Dunner	211039	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211039	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Week 8	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211039	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	211040	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211040	Screen	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	211109	Screen	MCSOD: BACTERIA OCCASIONAL
			MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211109	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211040	Week 8	MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211040	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	211109	Week 4	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	211110	Screen	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211110	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211145	Screen	MCSOD: HYALINE CASTS 0-1
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211147	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	211146	Screen	MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211146	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211109	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211147	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211147	Unscheduled	LABURIDRG:THIS URINE HAS AN UNUSUALLY LOW CREATININE (LESS THAN 200 MG/L).
	211146	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211110	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61082	Week 8	MCSOD: AMORPHOUS SEDIMENT NO SPECIMEN RECEIVED
			MCSOD: AMMONIUM URATES NO SPECIMEN RECEIVED
			MCSOD: BACTERIA NO SPECIMEN RECEIVED
			MCSOD: COARSE GRANULAR CAST NO SPECIMEN RECEIVED
			MCSOD: CALCIUM OXALATE CRYS NO SPECIMEN RECEIVED
			MCSOD: FINE GRANULAR CASTS NO SPECIMEN RECEIVED
			MCSOD: FATTY CASTS NO SPECIMEN RECEIVED
			MCSOD: HYALINE CASTS NO SPECIMEN RECEIVED
			MCSOD: MUCOUS THREADS NO SPECIMEN RECEIVED
			MCSOD: RBC CASTS NO SPECIMEN RECEIVED
			MCSOD: ROUND EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SQUAMOUS EPITH CELLS NO SPECIMEN RECEIVED
Dunner	211146	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
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Inv. Name	Patient Number	Visit	Comments
Dunner	211146	Week 4	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	211110	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	211109	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211145	Week 8	MCSOD: HYALINE CASTS 3-5
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Fava	51114	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

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Inv. Name	Patient Number	Visit	Comments
Fava	51114	Screen	PGTST:PREGNANT FEMALES:
	51141	Week 4	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	51142	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	51113	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Fava	51113	Week 8	RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *
			RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
	51142	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Fava	51142	Screen	PGTST:PREGNANT FEMALES:
	51141	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	51114	Week 4	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
	51113	Week 4	MCSOD: BACTERIA OCCASIONAL
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Fava	51141	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MANY
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	51142	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Fava	51142	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	51113	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241031	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MANY
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241073	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	241074	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241074	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	241073	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	241074	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241074	Week 4	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
Liebowitz	91138	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
Ferguson	241073	Week 8	MCSOD: BACTERIA MANY
			MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241073	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Helfing	81004	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81003	Week 4	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Week 4	MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Week 4	GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
		Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Unscheduled	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Week 8	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Week 8	MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSAMP:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSBRB:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSBNZ:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSCOC:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMTD:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMTQ:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Week 8	DSOPT:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSPCD:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSPPP:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMRJ:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Week 8	PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
	81004	Week 4	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Week 4	MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Week 4	BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Week 4	PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
	81003	Unscheduled	MCSOD: AMORPHOUS SEDIMENT OCCASIONAL
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	81051	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81051	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81004	Unscheduled	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Week 8	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81103	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	81075	Week 4	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
	81076	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81076	Week 4	RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *
			RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
	81103	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
	81075	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			CLG:CANCELLED.

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Week 8	BILITG:CANCELLED.
			CRTG:CANCELLED.
			ASTG:CANCELLED.
			ALTG:CANCELLED.
			GLUC:CANCELLED.
			KG:CANCELLED.
			ALPG:CANCELLED.
			NAG:CANCELLED.
			CO2G:CANCELLED.
			URICG:CANCELLED.
			BUNG:CANCELLED.
			PGTST:CANCELLED.
			CLG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Week 8	BILITG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			CRTG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			ASTG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			ALTG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			GLUC:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			KG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			ALPG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			NAG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			CO2G:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			URICG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			BUNG:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			PGTST:SPECIMEN LEAKED IN TRANSIT; THE REMAINING
			CLG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Week 8	BILITG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			CRTG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			ASTG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			ALTG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			GLUC:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			KG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			ALPG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			NAG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			CO2G:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			URICG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			BUNG:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			PGTST:SPECIMEN VOLUME IS NOT SUFFICIENT TO PERFORM
			CLG:THE TEST(S) REQUESTED. THE TEST HAS BEEN

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Week 8	BILITG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			CRTG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			ASTG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			ALTG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			GLUC:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			KG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			ALPG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			NAG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			CO2G:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			URICG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			BUNG:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			PGTST:THE TEST(S) REQUESTED. THE TEST HAS BEEN
			PRTUG:VERIFIED BY REPEAT ANALYSIS

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Unscheduled	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81076	Week 8	MCSOD: AMORPHOUS SEDIMENT MANY
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81076	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81103	Week 8	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 32/Final visit	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81103	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81076	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81076	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81075	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Week 32/Final visit	RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81076	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81076	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81075	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81075	Screen	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81052	Week 8	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	81004	Week 32/Final visit	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81004	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	81051	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	81003	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81003	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Liebowitz	91005	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91006	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MANY
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91006	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	91005	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MANY
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91005	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	91035	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MANY
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91097	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91097	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	91138	Week 8	PGTST:MALES AND NONPREGNANT
	91137	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91137	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91097	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91035	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91035	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91006	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	91097	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	91138	Screen	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91138	Screen	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	91097	Week 8	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91097	Week 8	MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	91137	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91138	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
		Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Barbee	21053	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
Londborg	101009	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: HYALINE CASTS 0-1
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101009	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
		Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101009	Screen	PGTST:PREGNANT FEMALES:
	101010	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	101044	Week 4	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101043	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	101044	Week 8	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			BILIUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101044	Week 8	PGTST:PREGNANT FEMALES:
	101043	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	101009	Week 8	PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101009	Week 8	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Barbee	21053	Week 8	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311115	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
Londborg	101044	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101044	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	101010	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101010	Week 8	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	101044	Unscheduled	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101044	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	101010	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	101043	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101043	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Lydiard	221129	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311115	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311115	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
Lydiard	221034	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	221033	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311115	Week 32/Final visit	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311115	Week 32/Final visit	PGTST:PREGNANT FEMALES:
Gilmer	61082	Week 8	MCSOD: SULFA-LIKE CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: TRIPLE PHOSPH. CRYS NO SPECIMEN RECEIVED
			MCSOD: TRICHOMONAS NO SPECIMEN RECEIVED
			MCSOD: URIC ACID CRYSTALS NO SPECIMEN RECEIVED
Lydiard	221130	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221130	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	221033	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 32/Final	MCSOD: AMORPHOUS SEDIMENT NO SPECIMEN RECEIVED
		visit	MCSOD: AMMONIUM URATES NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	MCSOD: BACTERIA NO SPECIMEN RECEIVED
			MCSOD: COARSE GRANULAR CAST NO SPECIMEN RECEIVED
			MCSOD: CALCIUM OXALATE CRYS NO SPECIMEN RECEIVED
			MCSOD: FINE GRANULAR CASTS NO SPECIMEN RECEIVED
			MCSOD: FATTY CASTS NO SPECIMEN RECEIVED
			MCSOD: HYALINE CASTS NO SPECIMEN RECEIVED
			MCSOD: MUCOUS THREADS NO SPECIMEN RECEIVED
			MCSOD: RBC CASTS NO SPECIMEN RECEIVED
			MCSOD: ROUND EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SQUAMOUS EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SULFA-LIKE CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: TRIPLE PHOSPH. CRYS NO SPECIMEN RECEIVED
			MCSOD: TRICHOMONAS NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	MCSOD: URIC ACID CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: WAXY CASTS NO SPECIMEN RECEIVED
			MCSOD: WBC CASTS NO SPECIMEN RECEIVED
			MCSOD: YEAST CELLS NO SPECIMEN RECEIVED
			DSAMP:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBRB:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBNZ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSCOC:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMTD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMTQ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSOPT:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSPCD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSPPP:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	DSMRJ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSAMP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSBRB:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSBNZ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSCOC:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTQ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSOPT:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPCD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPPP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMRJ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSAMP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSBRB:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	DSBNZ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSCOC:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMTD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMTQ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSOPT:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPCD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPPP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMRJ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSAMP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSBRB:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSBNZ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSCOC:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMTD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	DSMTQ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSOPT:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPCD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPPP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMRJ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSAMP:NO SPECIMEN RECEIVED
			DSBRB:NO SPECIMEN RECEIVED
			DSBNZ:NO SPECIMEN RECEIVED
			DSCOC:NO SPECIMEN RECEIVED
			DSMTD:NO SPECIMEN RECEIVED
			DSMTQ:NO SPECIMEN RECEIVED
			DSOPT:NO SPECIMEN RECEIVED
			DSPCD:NO SPECIMEN RECEIVED

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	DSPPP:NO SPECIMEN RECEIVED
			DSMRJ:NO SPECIMEN RECEIVED
			CHRTG:NO SPECIMEN RECEIVED
			BILIUG:NO SPECIMEN RECEIVED
			UROBLG:NO SPECIMEN RECEIVED
			COLORG:NO SPECIMEN RECEIVED
			GLCUG:NO SPECIMEN RECEIVED
			KETUG:NO SPECIMEN RECEIVED
			WBCUCG:NO SPECIMEN RECEIVED
			NITUG:NO SPECIMEN RECEIVED
			BLDUG:NO SPECIMEN RECEIVED
			PRTUG:NO SPECIMEN RECEIVED
			RBCUG:NO SPECIMEN RECEIVED

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Week 32/Final visit	RSUG:NO SPECIMEN RECEIVED
			WBCUG:NO SPECIMEN RECEIVED
			SPGRG:NO SPECIMEN RECEIVED
	221130	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	221129	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221034	Week 8	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	221033	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
	221034	Screen	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221034	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			RETG:THE TEST HAS BEEN CANCELLED.
			RETG:UNABLE TO LOCATE SPECIMEN IN LABORATORY.
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	221033	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Lydiard	221033	Unscheduled	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Gilmer	61082	Week 8	MCSOD: WAXY CASTS NO SPECIMEN RECEIVED
Lydiard	221033	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
McGrath	111171	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	111058	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	111171	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: COARSE GRANULAR CAST 0-1

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
McGrath	111171	Screen	MCSOD: HYALINE CASTS 0-1
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *
			RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	111058	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
McGrath	111058	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	111171	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	111058	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
McGrath	111058	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	111171	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Moreines	121007	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Moreines	121007	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 8	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Moreines	121007	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS OCCASIONAL
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Moreines	121007	Week 32/Final visit	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Munjack	131125	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	131144	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131144	Screen	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131012	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131011	Screen	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
	131012	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	131126	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131126	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			GLUC:SPECIMEN SLIGHTLY HEMOLYZED.
	131072	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131125	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131125	Screen	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131072	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS OCCASIONAL
	131071	Week 4	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	131072	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131072	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131012	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131071	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131071	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131011	Week 8	MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131143	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131143	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131126	Week 4	MCSOD: AMORPHOUS SEDIMENT NO SPECIMEN RECEIVED
			MCSOD: AMMONIUM URATES NO SPECIMEN RECEIVED
			MCSOD: BACTERIA NO SPECIMEN RECEIVED
			MCSOD: COARSE GRANULAR CAST NO SPECIMEN RECEIVED
			MCSOD: CALCIUM OXALATE CRYS NO SPECIMEN RECEIVED
			MCSOD: FINE GRANULAR CASTS NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131126	Week 4	MCSOD: FATTY CASTS NO SPECIMEN RECEIVED
			MCSOD: HYALINE CASTS NO SPECIMEN RECEIVED
			MCSOD: MUCOUS THREADS NO SPECIMEN RECEIVED
			MCSOD: RBC CASTS NO SPECIMEN RECEIVED
			MCSOD: ROUND EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SQUAMOUS EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SULFA-LIKE CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: TRIPLE PHOSPH. CRYS NO SPECIMEN RECEIVED
			MCSOD: TRICHOMONAS NO SPECIMEN RECEIVED
			MCSOD: URIC ACID CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: WAXY CASTS NO SPECIMEN RECEIVED
			MCSOD: WBC CASTS NO SPECIMEN RECEIVED
			MCSOD: YEAST CELLS NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131126	Week 4	CHRTG:NO SPECIMEN RECEIVED
			BILIUG:NO SPECIMEN RECEIVED
			UROBLG:NO SPECIMEN RECEIVED
			COLORG:NO SPECIMEN RECEIVED
			GLCUG:NO SPECIMEN RECEIVED
			KETUG:NO SPECIMEN RECEIVED
			WBCUCG:NO SPECIMEN RECEIVED
			NITUG:NO SPECIMEN RECEIVED
			BLDUG:NO SPECIMEN RECEIVED
			PRTUG:NO SPECIMEN RECEIVED
			RBCUG:NO SPECIMEN RECEIVED
			RSUG:NO SPECIMEN RECEIVED
			WBCUG:NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131126	Week 4	SPGRG:NO SPECIMEN RECEIVED
			PHUG:NO SPECIMEN RECEIVED
	131143	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
	131125	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 32/Final visit	MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131125	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131011	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131126	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131126	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	131143	Week 8	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131143	Week 8	PGTST:PREGNANT FEMALES:
	131012	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	131144	Week 8	MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Munjack	131144	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	131126	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
Nelson	141041	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Nelson	141041	Week 4	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Nelson	141041	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Rapaport	151037	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151037	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151038	Screen	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151038	Unscheduled	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151085	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151086	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151086	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151095	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151096	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151096	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151038	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	151085	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151099	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Unscheduled	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151100	Screen	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151100	Screen	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	151086	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151095	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	151096	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	151038	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	151086	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151086	Week 8	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	151099	Week 4	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	151100	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	151096	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151096	Week 8	DSAMP:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSBRB:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSBNZ:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSCOC:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMTD:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMTQ:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSOPT:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSPCD:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSPPP:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSMRJ:PER CLIENT - NO SPECIMEN COLLECTED/SENT
	151095	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151095	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151096	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151099	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151099	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151096	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
	151100	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MANY
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
	151096	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
	151117	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151117	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	151096	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151095	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151095	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
	151118	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	151153	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151153	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151038	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	151117	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	151037	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151037	Week 32/Final visit	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151095	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			NEUTG:VERIFIED BY REPEAT ANALYSIS
	151099	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	151118	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151118	Week 4	MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151117	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151099	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151099	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
	151118	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	151099	Week 32/Final visit	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Gilmer	61082	Week 8	MCSOD: WBC CASTS NO SPECIMEN RECEIVED

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61082	Week 8	MCSOD: YEAST CELLS NO SPECIMEN RECEIVED
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			CHRTG:NO SPECIMEN RECEIVED
			BILIUG:NO SPECIMEN RECEIVED
			UROBLG:NO SPECIMEN RECEIVED
			COLORG:NO SPECIMEN RECEIVED
Walsh	171015	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171015	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171027	Screen	MCSOD: BACTERIA OCCASIONAL
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171016	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171016	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171015	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	171061	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171061	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171027	Week 4	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171027	Week 4	MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171027	Week 4	GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
	171028	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171028	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171064	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171064	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171063	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171064	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171064	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
	171063	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171062	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171062	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171063	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
	171064	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171015	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171015	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
	171062	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	171063	Screen	MCSOD: AMORPHOUS SEDIMENT FEW

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171063	Screen	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	171062	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171062	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	171061	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171015	Week 32/Final visit	PGTST:POSITIVE
	171061	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	171028	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171028	Week 8	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	171015	Week 32/Final visit	PGTST:PREGNANT FEMALES:
	171027	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171027	Week 8	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Thase	181083	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Gilmer	61082	Week 8	GLCUG:NO SPECIMEN RECEIVED
			KETUG:NO SPECIMEN RECEIVED
			WBCUCG:NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61082	Week 8	NITUG:NO SPECIMEN RECEIVED
Walsh	171016	Unscheduled	CLG:NO SPECIMEN RECEIVED
			BILITG:NO SPECIMEN RECEIVED
			CRTG:NO SPECIMEN RECEIVED
			ASTG:NO SPECIMEN RECEIVED
			ALTG:NO SPECIMEN RECEIVED
			GLUC:NO SPECIMEN RECEIVED
			KG:NO SPECIMEN RECEIVED
			ALPG:NO SPECIMEN RECEIVED
			NAG:NO SPECIMEN RECEIVED
			CO2G:NO SPECIMEN RECEIVED
			URICG:NO SPECIMEN RECEIVED
			BUNG:NO SPECIMEN RECEIVED

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171016	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	171015	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Thase	181084	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181084	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	181083	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	181105	Screen	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181105	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	181135	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181135	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	181136	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181136	Screen	RETG:* TEST HAS BEEN CANCELLED. *
			RETG:* TEST NOT PERFORMED. *
			RETG:* TO THE AGE OF THE SPECIMEN. *
			RETG:* UNSUITABLE FOR ANALYSIS DUE *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	181106	Unscheduled	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181106	Unscheduled	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	181084	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	181135	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	181136	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181136	Week 8	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	181135	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181135	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	181136	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	181105	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181105	Week 8	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Gilmer	61082	Week 8	BLDUG:NO SPECIMEN RECEIVED
			PRTUG:NO SPECIMEN RECEIVED
			RBCUG:NO SPECIMEN RECEIVED

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61082	Week 8	RSUG:NO SPECIMEN RECEIVED
			WBCUG:NO SPECIMEN RECEIVED
			SPGRG:NO SPECIMEN RECEIVED
			PHUG:NO SPECIMEN RECEIVED
Thase	181106	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
Ferguson	241032	Screen	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
Thase	181106	Screen	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	181105	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181105	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	181083	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	181084	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Thase	181084	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
Trivedi	191014	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 8	MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191014	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Zajecka	201067	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	201068	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			UROBLG:CANCELLED.
			UROBLG:SPECIMEN ACCIDENTALLY DISCARDED BEFORE ALL
			UROBLG:TESTING WAS COMPLETED. THE TEST HAS BEEN

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201068	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	201123	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201123	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	201092	Unscheduled	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201092	Week 8	PGTST:MALES AND NONPREGNANT
	201123	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	201092	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	201068	Week 32/Final	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
		visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
	201123	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201123	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	201092	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201092	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
	201068	Week 32/Final visit	PGTST:PREGNANT FEMALES:
	201092	Screen	PGTST:PREGNANT FEMALES:
	201068	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
Ferguson	241032	Screen	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241032	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Zajecka	201068	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201068	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	201067	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	201068	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201068	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Amsterdam	11159	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11159	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	11160	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	11167	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11167	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	11160	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	11167	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11159	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	11134	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11167	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	11133	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11133	Week 8	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	11160	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: HYALINE CASTS 0-1
			MCSOD: MUCOUS THREADS MODERATE
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	11133	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	11134	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11133	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Barbee	21053	Screen	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: MUCOUS THREADS FEW
			PRTUG:VERIFIED BY REPEAT ANALYSIS
Ferguson	241032	Screen	PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Ferguson	241032	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Helfing	81052	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
Delgado	41069	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41069	Screen	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	41070	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	41094	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
Helfing	81052	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Helfing	81052	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
Delgado	41094	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	41069	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	41070	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41070	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	41093	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
		Unscheduled	MCSOD: CALCIUM OXALATE CRYS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41093	Unscheduled	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Week 32/Final visit	MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	41094	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41094	Week 32/Final visit	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	41093	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41093	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	41094	Week 4	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	41093	Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	41070	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	41093	Screen	MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS OCCASIONAL

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41093	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	41069	Week 4	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
DuBoff	311017	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311017	Unscheduled	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
	311018	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311018	Screen	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	311017	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	311115	Week 4	MCSOD: AMORPHOUS SEDIMENT MANY
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	311017	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311017	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Helfing	81052	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Liebowitz	91098	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Liebowitz	91098	Week 8	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Screen	MCSOD: AMORPHOUS SEDIMENT FEW
DuBoff	311115	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311115	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Liebowitz	91098	Screen	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311018	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311018	Week 4	PRTUG:VERIFIED BY REPEAT ANALYSIS
	311115	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	311017	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311017	Unscheduled	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Liebowitz	91098	Screen	PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61081	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Screen	MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61081	Screen	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	61082	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Gilmer	61082	Screen	PGTST:PREGNANT FEMALES:
McGrath	111057	Unscheduled	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Trivedi	191013	Screen	MCSOD: BACTERIA OCCASIONAL
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 8	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
Halbreich	71077	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE

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Inv. Name	Patient Number	Visit	Comments
Halbreich	71077	Week 4	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
Hoopes	271021	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
	271022	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *

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Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Screen	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	271021	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			DSAMP:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBRB:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBNZ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSCOC:*EMPLOYMENT EVALUATIVE PURPOSES. *

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All Enrolled Patients

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Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	DSMTD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMTQ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSOPT:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSPCD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSPPP:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMRJ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSAMP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
Hoopes	271022	Unscheduled	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	MCSOD: AMORPHOUS SEDIMENT NO SPECIMEN RECEIVED
			MCSOD: AMMONIUM URATES NO SPECIMEN RECEIVED
			MCSOD: BACTERIA NO SPECIMEN RECEIVED
			MCSOD: COARSE GRANULAR CAST NO SPECIMEN RECEIVED
			MCSOD: CALCIUM OXALATE CRYS NO SPECIMEN RECEIVED
			MCSOD: FINE GRANULAR CASTS NO SPECIMEN RECEIVED
			MCSOD: FATTY CASTS NO SPECIMEN RECEIVED
			MCSOD: HYALINE CASTS NO SPECIMEN RECEIVED
			MCSOD: MUCOUS THREADS NO SPECIMEN RECEIVED
			MCSOD: RBC CASTS NO SPECIMEN RECEIVED
			MCSOD: ROUND EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SQUAMOUS EPITH CELLS NO SPECIMEN RECEIVED
			MCSOD: SULFA-LIKE CRYSTALS NO SPECIMEN RECEIVED

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	MCSOD: TRIPLE PHOSPH. CRYS NO SPECIMEN RECEIVED
			MCSOD: TRICHOMONAS NO SPECIMEN RECEIVED
			MCSOD: URIC ACID CRYSTALS NO SPECIMEN RECEIVED
			MCSOD: WAXY CASTS NO SPECIMEN RECEIVED
			MCSOD: WBC CASTS NO SPECIMEN RECEIVED
			MCSOD: YEAST CELLS NO SPECIMEN RECEIVED
			DSAMP:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBRB:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSBNZ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSCOC:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMTD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMTQ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSOPT:*EMPLOYMENT EVALUATIVE PURPOSES. *

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Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	DSPCD:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSPPP:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSMRJ:*EMPLOYMENT EVALUATIVE PURPOSES. *
			DSAMP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSBRB:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSBNZ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSCOC:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTQ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSOPT:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPCD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPPP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMRJ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	DSAMP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSBRB:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSBNZ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSCOC:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMTD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMTQ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSOPT:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPCD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPPP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMRJ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSAMP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSBRB:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSBNZ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	DSCOC:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMTD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMTQ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSOPT:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPCD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPPP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMRJ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSAMP:NO SPECIMEN RECEIVED
			DSBRB:NO SPECIMEN RECEIVED
			DSBNZ:NO SPECIMEN RECEIVED
			DSCOC:NO SPECIMEN RECEIVED
			DSMTD:NO SPECIMEN RECEIVED
			DSMTQ:NO SPECIMEN RECEIVED

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	DSOPT:NO SPECIMEN RECEIVED
			DSPCD:NO SPECIMEN RECEIVED
			DSPPP:NO SPECIMEN RECEIVED
			DSMRJ:NO SPECIMEN RECEIVED
			CHRTG:NO SPECIMEN RECEIVED
			BILIUG:NO SPECIMEN RECEIVED
			UROBLG:NO SPECIMEN RECEIVED
			COLORG:NO SPECIMEN RECEIVED
			GLCUG:NO SPECIMEN RECEIVED
			KETUG:NO SPECIMEN RECEIVED
			WBCUCG:NO SPECIMEN RECEIVED
			NITUG:NO SPECIMEN RECEIVED
			BLDUG:NO SPECIMEN RECEIVED

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 8	PRTUG:NO SPECIMEN RECEIVED
			RBCUG:NO SPECIMEN RECEIVED
			RSUG:NO SPECIMEN RECEIVED
			WBCUG:NO SPECIMEN RECEIVED
			SPGRG:NO SPECIMEN RECEIVED
			PHUG:NO SPECIMEN RECEIVED
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	271045	Week 4	MCSOD: MUCOUS THREADS MODERATE
			ALPG:AGE ALKALINE PHOSPHATASE LEVELS
			ALPG:IN INDIVIDUALS 12-18 YEARS OF

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271045	Week 4	ALPG:MAXIMUM BONE GROWTH.
			ALPG:VARY ACCORDING TO THE PERIOD OF
	271022	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	271045	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			ALPG:AGE ALKALINE PHOSPHATASE LEVELS
			ALPG:IN INDIVIDUALS 12-18 YEARS OF
			ALPG:MAXIMUM BONE GROWTH.

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271045	Screen	ALPG:VARY ACCORDING TO THE PERIOD OF
Prover	261023	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Week 4	MCSOD: BACTERIA MODERATE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Prover	261023	Week 4	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
		Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Smith	281025	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281025	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281026	Screen	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281026	Screen	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281102	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281102	Screen	PGTST:PREGNANT FEMALES:
	281101	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281107	Screen	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281107	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	281026	Week 8	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281102	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281107	Week 4	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	281102	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Trivedi	191013	Week 8	DSBRB:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
Smith	281101	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281101	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Trivedi	191013	Week 8	DSBNZ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
Smith	281101	Week 8	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281108	Week 4	MCSOD: BACTERIA MODERATE
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	281102	Week 8	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

LIST12

M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281102	Week 8	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281108	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: HYALINE CASTS 0-1
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281108	Week 8	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
Trivedi	191013	Week 8	DSCOC:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMTQ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSOPT:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPCD:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSPPP:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSMRJ:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			DSAMP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSBRB:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSBNZ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSCOC:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	DSMTD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMTQ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSOPT:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPCD:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSPPP:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSMRJ:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			DSAMP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Smith	281025	Week 8	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
	281102	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281102	Week 4	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281101	Week 4	MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281108	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281108	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	281026	Week 4	MCSOD: BACTERIA FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
	281025	Week 8	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			PRTUG:VERIFIED BY REPEAT ANALYSIS
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281025	Week 8	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Oldroyd	321055	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
	321056	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Oldroyd	321056	Screen	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	321087	Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	321055	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Oldroyd	321055	Week 4	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
	321087	Week 4	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
		Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Oldroyd	321087	Week 8	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PRTUG:VERIFIED BY REPEAT ANALYSIS
Dunner	211147	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: BACTERIA FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211147	Week 8	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Ferguson	241074	Week 8	MCSOD: BACTERIA MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Londborg	101043	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Londborg	101043	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Rapaport	151100	Week 8	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Rapaport	151100	Week 8	PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	151153	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Walsh	171062	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS MANY (21 OR GREATER)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Walsh	171062	Week 32/Final visit	LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Zajecka	201067	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT MODERATE
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311018	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
DuBoff	311018	Week 8	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Gilmer	61081	Week 8	PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Hoopes	271022	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			DSAMP:NO SPECIMEN RECEIVED
			DSBRB:NO SPECIMEN RECEIVED
			DSBNZ:NO SPECIMEN RECEIVED
			DSCOC:NO SPECIMEN RECEIVED
			DSMTD:NO SPECIMEN RECEIVED
			DSMTQ:NO SPECIMEN RECEIVED
			DSOPT:NO SPECIMEN RECEIVED
			DSPCD:NO SPECIMEN RECEIVED
			DSPPP:NO SPECIMEN RECEIVED
			DSMRJ:NO SPECIMEN RECEIVED
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Hoopes	271022	Week 32/Final visit	PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
	271045	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			ALPG:AGE ALKALINE PHOSPHATASE LEVELS
			ALPG:IN INDIVIDUALS 12-18 YEARS OF
			ALPG:MAXIMUM BONE GROWTH.
			ALPG:VARY ACCORDING TO THE PERIOD OF
Smith	281026	Week 8	MCSOD: MUCOUS THREADS FEW

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281026	Week 8	MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
	281107	Week 8	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	281108	Week 32/Final visit	MCSOD: MUCOUS THREADS FEW

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Smith	281108	Week 32/Final visit	MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Trivedi	191013	Week 8	DSBRB:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSBNZ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSCOC:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMTD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	DSMTQ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSOPT:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPCD:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSPPP:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSMRJ:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			DSAMP:NO SPECIMEN RECEIVED
			DSBRB:NO SPECIMEN RECEIVED
			DSBNZ:NO SPECIMEN RECEIVED
			DSCOC:NO SPECIMEN RECEIVED
			DSMTD:NO SPECIMEN RECEIVED
			DSMTQ:NO SPECIMEN RECEIVED
			DSOPT:NO SPECIMEN RECEIVED
			DSPCD:NO SPECIMEN RECEIVED

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	DSPPP:NO SPECIMEN RECEIVED
			DSMRJ:NO SPECIMEN RECEIVED
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

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Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Week 8	RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Unscheduled	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Trivedi	191013	Unscheduled	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
DuBoff	311116	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Dunner	211145	Week 8	PRTUG:VERIFIED BY REPEAT ANALYSIS
Lydiard	221033	Week 32/Final visit	PHUG:NO SPECIMEN RECEIVED
Liebowitz	91036	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Zajecka	201091	Screen	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Zajecka	201091	Screen	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
		Unscheduled	MCSOD: MUCOUS THREADS FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)
Amsterdam	11065	Screen	MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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M2020-0034: Reboxetine vs. Placebo in Major Depression Resistant to Fluoxetine

Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11066	Week 4	MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

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Inv. Name	Patient Number	Visit	Comments
Amsterdam	11066	Week 4	MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11066	Week 4	NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
		Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11066	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS FEW
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
		Screen	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
	11065	Week 4	MCSOD: AMORPHOUS SEDIMENT PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: AMMONIUM URATES PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: BACTERIA PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11065	Week 4	MCSOD: COARSE GRANULAR CAST PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: CALCIUM OXALATE CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FINE GRANULAR CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: FATTY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: HYALINE CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: MUCOUS THREADS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: RBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: ROUND EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SQUAMOUS EPITH CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: SULFA-LIKE CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRIPLE PHOSPH. CRYS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: TRICHOMONAS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: URIC ACID CRYSTALS PER CLIENT - NO SPECIMEN COLLECTED/SENT

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All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11065	Week 4	MCSOD: WAXY CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: WBC CASTS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			MCSOD: YEAST CELLS PER CLIENT - NO SPECIMEN COLLECTED/SENT
			CHRTG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BILIUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			UROBLG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			COLORG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			GLCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			KETUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUCG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			NITUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			BLDUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PRTUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Amsterdam	11065	Week 4	RBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			RSUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			WBCUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			SPGRG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
			PHUG:PER CLIENT - NO SPECIMEN COLLECTED/SENT
	11134	Week 8	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			LABURIDRG:* EVALUATIVE PURPOSES. *
			LABURIDRG:* HANDLING. THESE RESULTS SHOULD BE USED FOR MEDICAL *
			LABURIDRG:* PURPOSES ONLY AND NOT FOR ANY LEGAL OR EMPLOYMENT *
			LABURIDRG:* SPECIMEN ANALYSIS WAS PERFORMED WITHOUT CHAIN OF CUSTODY *
Delgado	41069	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: SQUAMOUS EPITH CELLS FEW (1-5)

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Delgado	41069	Week 32/Final visit	LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
			PGTST:FEMALES: NEGATIVE
			PGTST:MALES AND NONPREGNANT
			PGTST:POSITIVE
			PGTST:PREGNANT FEMALES:
Croft	231120	Week 32/Final visit	MCSOD: AMORPHOUS SEDIMENT FEW
			MCSOD: MUCOUS THREADS MODERATE
			MCSOD: SQUAMOUS EPITH CELLS MODERATE (6-20)
			LABURIDRG:*EMPLOYMENT EVALUATIVE PURPOSES. *
			LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *

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Comments in Lab Data
All Enrolled Patients

Date Produced: January 15, 2001

Inv. Name	Patient Number	Visit	Comments
Croft	231120	Week 32/Final visit	LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *
Fava	51114	Week 4	LABURIDRG:*HAVE BEEN HANDLED AS A LEGAL SPECIMEN. RESULTS SHOULD BE *
			LABURIDRG:*SPECIMEN WAS RECEIVED WITHOUT CHAIN OF CUSTODY AND MAY NOT *
			LABURIDRG:*USED FOR MEDICAL PURPOSES ONLY AND NOT FOR ANY LEGAL OR *