DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-033 **NDA APPROVAL**

Solvay Pharmaceuticals, Inc.
Attention: Michael Hare
Assistant Director, Regulatory Affairs
901 Sawyer Road
Marietta, GA 30062

Dear Mr. Hare:

Please refer to your new drug application dated April 28, 2006, received May 1, 2006, submitted under 505(b) of the Federal Food, Drug and Cosmetics Act for Luvox CR (fluvoxamine maleate) 100mg and 150mg Extended-Release Capsules.

We acknowledge receipt of your submissions dated December 28, 2007, January 11, 2008, and January 17, 2008.

The December 28, 2007 submission constituted a complete response to our December 20, 2007 action letter.

This new drug application provides for the use of Luvox CR (fluvoxamine maleate) Extended-Release Capsules for the treatment of social anxiety disorder (SAD) and obsessive compulsive disorder (OCD).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert and Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-033."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-033**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for the indication of social anxiety disorder for ages 0-11 years because the necessary studies are impossible or highly impracticable because there are not enough patients in that age group with the disease to study. We are deferring submission of your pediatric studies for ages 12-17 years because the drug is ready for approval for use in adults and the pediatric studies have not been completed.

We note that this product is already fully labeled for use in all appropriate pediatric populations for the indication of obsessive compulsive disorder using the immediate-release formulation. Therefore, no additional pediatric studies are needed at this time.

Your deferred pediatric studies required under 505B(a) of the Food, Drug, and Cosmetic Act are required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Food, Drug, and Cosmetic Act. These commitments are listed below.

POSTMARKETING COMMITMENTS

We remind you of your following postmarketing study commitments agreed upon in your submission dated December 29, 2007 and February 20, 2008. These commitments are listed below.

1. Deferred Pediatric Studies Under PREA

   You are required to assess the safety and effectiveness of Luvox CR (fluvoxamine maleate) Extended-Release Capsules as a treatment for social anxiety disorder in pediatric patients ages 12 to 17 (children and adolescents).

   Submission of Pediatric Assessment Plan: June 2008
   Final Report Submission: 3 years from the date of approval

   Submit final study reports to this NDA. For administrative purposes, all submissions related to this/these pediatric postmarketing study commitment(s) must be clearly designated "**Required Pediatric Study Commitments**".

2. Microscopic Examination of the Standard Battery of Tissues used in the General Toxicity Study

   We note your commitment to conduct and provide a complete report of the microscopic examination of the remaining standard battery of tissues from the toxicity study entitled "Fluvoxamine Maleate: 14-Day Oral (Gavage) Administration Comparative Toxicity Study in the Rat with Fluvoxamine Maleate and Fluvoxamine Maleate Spiked with [redacted]

Final Report Submission: June 2008

3. Maintenance Study for Social Anxiety Disorder

Although your NDA for fluvoxamine maleate CR demonstrates effectiveness as a treatment for social anxiety disorder over an interval of 12 weeks, it does not provide information about the duration and conditions of treatment that are necessary to sustain effects over an extended duration. While it is widely assumed that continued treatment of symptomatically remitted patients with social anxiety disorder reduces their risk of relapse, we have no evidence that fluvoxamine maleate CR has efficacy after 12 weeks. You have agreed to conduct and submit the results of a randomized withdrawal study to address longer-term effectiveness and safety for your drug in social anxiety disorder. You have agreed to commit to conducting this study and submitting the results no later than 3 years after the date of approval for this NDA.

Final Report Submission: 3 years after the date of approval

DISSOLUTION METHOD AND SPECIFICATION

We acknowledge your agreement to adopt the following final dissolution method and specifications for all two capsule strengths, 100 mg, and 150 mg:

USP Apparatus 2:	Paddle Method
RPMs:	50 rpm
Volume:	900 mL
Medium:	pH 6.8 Phosphate Buffer
Sampling Times:	2, 4, 8, and 12 hours

Time	% Released
2h	
4h	
8h	
12h	

EXPIRY DATE

An expiration date of 24 months has been assigned for this product based on the provided drug product stability data.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LCDR Renmeet Grewal, Pharm.D., Senior Regulatory Project Manager, at (301) 796-1080.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: Package Insert & Medguide

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
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