CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-519

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-519

NDA APPROVAL

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

Dear Mr. Hare:

Please refer to your new drug application (NDA) dated June 28, 2002, received on July 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Luvox (fluvoxamine maleate) 25mg, 50mg and 100mg tablets.

We acknowledge receipt of your submissions dated June 18, 2007, June 20, 2007, July 20, 2007, August 8, 2007, and November 19, 2007.

Your June 20, 2007 submission constituted a complete response to our letter dated November 16, 2006.

This new drug application provides for the use of Luvox (fluvoxamine maleate) 25mg, 50mg and 100mg tablets for the treatment of obsessions and compulsions in patients with 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.

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. You are also responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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. 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 21-519."

Dissolution Method and Specification
We note your acceptance of our proposed dissolution methodology and specification (below) for all tablet strengths. As previously conveyed to you, your proposal to sample at only 30 min (Q= [redacted] in 30 min) is acceptable. b(4)

Medium: 900 ml water at 37 o C
Apparatus II : [redacted]; at 50 rpm b(4)
Sampling Times: 10, 20 and 30 min
Q = [redacted] in 30 min

POSTMARKETING COMMITMENTS
We remind you of your postmarketing study commitments agreed to in your e-mail communication dated December 17, 2007. These commitments are listed below:

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

   You did not conduct microscopic examination of the standard battery of tissues in the general 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] and [redacted] We note your commitment to provide the Agency with this report. b(4)

   Final Report Submission: by June 2008

2. **Juvenile Animal Study**

   We note your commitment to conduct a juvenile animal study in rats.

   Final Report Submission: by March 2008

Please submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to these postmarketing study commitments should be prominently labeled "**Postmarketing Study Commitment Protocol**", "**Postmarketing Study Commitment Final Report**", or "**Postmarketing Study Commitment Correspondence.**"

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:

Food and Drug Administration

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.

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

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 CDR Bill Bender, Regulatory Project Manager, at (301) 796-2145.

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

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
12/20/2007 08:33:19 AM