DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 20-243/S-021

Solvay Pharmaceuticals
Attention: J. Greg Perkins, Ph.D.
Vice President Regulatory Science
901 Sawyer Road
Marietta, Georgia 30062

Dear Dr. Perkins:

Please refer to your supplemental new drug application dated and received December 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Luvox (fluvoxamine maleate) 25 mg, 50 mg, and 100 mg Tablets.

Additionally, we acknowledge receipt of your submissions dated May 31, and June 30, 2000.

Reference is also made to an Agency letter dated March 25, 1997, providing for the approval of supplemental application S-006 to use Luvox to treat obsessive compulsive disorder in the pediatric population. This letter also committed that Solvay explore further the effects of Luvox in obsessive compulsive disorder (OCD) patients between the ages of 12 – 17 years old as a Phase 4 commitment.

We additionally refer to a series of faxes dated September 21, 24, and 26, 2000 in which labeling for this supplemental application, S-021, was agreed upon by Solvay and the Agency.

This supplemental new drug application provides for revised labeling of Luvox based upon the results of a long-term, open-label safety study and a pharmacokinetic study in children and adolescents with OCD.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

Additionally, this data completely fulfills your Phase 4 commitment for S-006 as enumerated in our March 25, 1997, Agency letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit 20 paper copies of the final printed labeling ten of which are individually mounted on heavy weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-243/S-021". Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely,

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment