DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-936/S-070

Eli Lilly and Company
Attention: Gregory T. Brophy, Ph.D.
Lilly Corporate Center
Indianapolis, IN 46285-2643

Dear Dr. Brophy:

We acknowledge receipt of your supplemental new drug application dated August 18, received August 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sarafem (fluoxetine hydrochloride) 10 mg and 20 mg pulvules .

The above supplemental application, submitted under "Changes Being Effected", provides for the following revisions to product labeling:

1. The addition of a new subsection under **WARNINGS** entitled **Clinical Worsening and Suicide Risk**.
2. Revisions to the **PRECAUTIONS-Information for Patients** section regarding clinical worsening.
3. Deletion of the section in **PRECAUTIONS-General** entitled "Suicide".
4. Add a reference to the **WARNINGS** section at the end of the **PRECAUTIONS- Pediatric Use** section, i.e., (see **WARNINGS-Clinical Worsening and Suicide Risk**).
5. The addition of a new subsection entitled **Discontinuation of Treatment with Sarafem** in the **PRECAUTIONS-General** section.
6. The addition of a new subsection entitled **Abnormal Bleeding** in the **PRECAUTIONS-General** section.
7. The relocation of the **Hyponatremia** subsection from the end of the **PRECAUTIONS** section to the **PRECAUTIONS-General** section.
8. The addition of an abnormal bleeding paragraph in the **PRECAUTIONS-Information for Patients** section.
9. The addition of a new subsection entitled **Drugs That Interfere With Hemostasis (Non-selective NSAIDs, Aspirin, Warfarin, etc.)** in the **PRECAUTIONS-Drug Interactions** section.
10. The addition of a new subsection entitled **Pregnancy-Nonteratogenic Effects** in the **PRECAUTIONS-Pregnancy** section.
11. The addition of a new subsection entitled **Treatment of Pregnant Women During the Third Trimester** in the **DOSAGE AND ADMINISTRATION-Special Populations** section.
12. The addition of a new subsection entitled **Discontinuation of Treatment with Sarafem** in the **DOSAGE AND ADMINISTRATION** section.

We have completed our review of supplemental applications 18-936/S-070, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted August 18, 2004), which incorporates all of the revisions made in the above supplement. Accordingly, this supplemental application is approved effective on the date of this letter.

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

*{See appended electronic signature page}*

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

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

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/s/

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Russell Katz

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