DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-936/S-086

Eli Lilly and Company
Attention: Lori de los Reyes, RN, MSN
Associate Regulatory Consultant
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Reyes:
Please refer to your supplemental new drug application dated January 10, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sarafem (fluoxetine HCl) Capsules.

This "Changes Being Effected" supplemental new drug application provides for new language to inform clinicians of the possible risk factors for and signs and symptoms of hyponatremia and to standardize the language across the SSRIs and SNRIs, as requested in the Agency letter of August 7, 2007.

Specifically, it provides for revisions under the PRECAUTIONS section, Hyponatremia subsection.

We have completed our review of this supplemental new drug application and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 10, 2008 (copy attached).

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

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

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 Renmeet Grewal, Pharm. D., 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

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
6/26/2008 01:38:52 PM