DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-936/S-089

Eli Lilly and Company
Attention: Kevin Sheehan, MS, PharmD
Senior Regulatory Associate, Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear D. Sheehan:

We acknowledge receipt of your supplemental new drug application dated February 19, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sarafem (fluoxetine HCl) capsules.

We additionally acknowledge receipt of your amendment dated May 11, 2009, providing for a correction to the labeling.

Reference is also made to an FDA letter dated December 4, 2008, notifying you, under section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for fluoxetine. This information pertains to the risk of neuroleptic malignant syndrome associated with use of selective serotonin reuptake inhibitors (SSRIs) or serotonin-norepinephrine reuptake inhibitors (SNRIs), including fluoxetine. Reference is also made to an e-mail correspondence from LCDR Sonny Saini, of the FDA, to you dated January 29, 2009, requesting that you delete the terms "serotonin syndrome" and "neuroleptic malignant syndrome-like events" from the Postintroduction Reports section of labeling since they are now discussed more prominently in the Warnings section. We additionally refer to your e-mail correspondence dated January 29, 2009 agreeing to the deletion of these terms from the Postintroduction Reports section of labeling.

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

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

We expect that the revised labeling would be available on your website within 10 days of receipt of this letter and that it would accompany any newly shipped product in a reasonable amount of time. Drug product already in distribution with currently approved labeling may remain in distribution.

Failure to make these changes within the specified period of time could make your product misbranded under 21 USC 321(n) and 352(a).

LETTERS TO HEALTH CARE PROFESSIONALS

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

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 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

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
6/22/2009 09:07:10 AM