DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 018936/S-106

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Anindita Sen, PhD
Director, Global Regulatory Affairs, US
Lilly Corporate Center
Drop Code 2543
Indianapolis, IN 46285

Dear Dr. Sen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received June 30, 2015, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Sarafem (fluoxetine hydrochloride) 10 mg and 20 mg Capsules.

We also refer to our letter dated June 3, 2015, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Sarafem capsules. This information pertains to the association between the use of antidepressants and angle-closure glaucoma.

This "Changes Being Effected" supplemental new drug application provides for the withdrawal of the Premenstrual Dysphoric Disorder (PMDD) indication for Sarafem capsules under NDA 018936.

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

Additionally, given the withdrawal of the PMDD indication, we are not requiring that you implement the safety labeling changes as communicated in our June 3, 2015 letter.

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 CAPT Terry Harrison, Safety Regulatory Project Manager, at (301) 796-2770 or terry.harrison@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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

/s/

MITCHELL V Mathis
11/24/2015