DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-520 / S-017

Eli Lilly and Company
Attention: Christine A. Phillips, Ph.D., RAC
Manager, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Phillips:

Please refer to your supplemental new drug applications dated and received January 24, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symbyax (olanzapine/fluoxetine HCl) Capsules.

These "Changes Being Effected" supplemental new drug applications provide for new language pertaining to the risk of bleeding events. The intent of the new language is to inform clinicians of the increased risk of bleeding events with SSRIs and SNRIs and to standardize the language across the SSRIs and SNRIs, as requested in the Agency letter of January 3, 2008. Specifically:

1. Revisions to PRECAUTIONS entitled Abnormal Bleeding.
2. Revision to Information for Patients.
3. Revisions to Drug Interactions entitled Drugs that Interfere with Hemostatsis.

We have completed our review of these supplemental new drug applications and they are approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on January 24, 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, email CAPT Steven D. Hardeman, R.Ph., Chief, Project Management Staff, at Steven.Hardeman@FDA.HHS.GOV.

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

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
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