DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-520 / S-009

Eli Lilly and Company
Attention: Robin Wojcieszek, R.Ph.
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms Wojcieszek:

Please refer to your supplemental new drug application dated April 6, 2006, received April 10, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Symbyax (olanzapine and fluoxetine HCl) capsules.

This "Changes Being Effected" supplemental new drug application provides for labeling changes as follows:

- Under the **PRECAUTIONS** section, **Transaminase Elevations** subsection, the following statement has been added -- "*Rare postmarketing reports of hepatitis have been received. Very rare cases of cholestatic or mixed liver injury have also been reported in the postmarketing period.*"

- Under the **ADVERSE REACTIONS** section, **Other Events Observed with Olanzapine or Fluoxetine Monotherapy** subsection, the term "*jaundice*" was added.

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 March 29, 2006 (copy attached).

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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