DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18-936/S-096
NDA 21-235/S-018

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Kevin C. Sheehan, M.S., Pharm.D.
Manager Global Regulatory Affairs-US
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Sheehan,

Please refer to your Supplemental New Drug Applications (sNDAs) dated April 8, 2011, received April 11, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prozac Pulvules (fluoxetine hydrochloride) capsules for oral use and Prozac Weekly (fluoxetine hydrochloride) delayed-release capsules.

These "Prior Approval" supplemental new drug applications propose changes to the following sections of the package insert:

- Under **WARNINGS AND PRECAUTIONS**, section **5.10**, **Use in Patients with Concomitant Illness**, added text related to cautious use in patients with Acute Narrow-Angle Glaucoma.
- Under **ADVERSE REACTIONS**
  - **section 6.1, Clinical Trials Experience,** Added text related to occasional persistence of sexual dysfunction following discontinuation of fluoxetine treatment.
  - **Section 6.3, Postmarketing Experience,** Added the term "memory impairment."

We have completed our review of these supplemental applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, email Kofi Ansah, Pharm.D., Senior Regulatory Project Manager, at Kofi.Ansah@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

ENCLOSURE:
Content of Labeling

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

/s/

THOMAS P LAUGHREN
06/15/2011