



NDA 18-936 S-083
NDA 20-101 S-038
NDA 21-235 S-010

Eli Lilly and Company
Attention: Lori de los Reyes, RN, MSN
Associate Regulatory Consultant
Lilly Corporate Center
Indianapolis, IN 46285

Dear Ms. Reyes:

Please refer to your supplemental new drug applications dated and received January 9, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prozac (fluoxetine HCl) Capsules, Solution, and Delayed Release Capsules.

These "Changes Being Effected" supplemental new drug applications provide for new language to inform clinicians of the possible risk factors for and signs and symptoms of hyponatremia and to standardize the language across the SSRIs and SNRIs, as requested in the Agency letter of August 7, 2007. Specifically:

1. Revisions under the PRECAUTIONS section, Hyponatremia subsection.
2. Revisions under the Geriatric Use section.

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 9, 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.

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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
3/9/2008 12:20:07 PM