



NDA 18-936 S-084
NDA 20-101 S-039
NDA 21-235 S-011

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 25, 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 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 Hemostasis.

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 25, 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.

NDA 18-936 S-084

NDA 20-101 S-039

NDA 21-235 S-011

Page 2

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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