DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-936/S-074
NDA 20-101/S-034
NDA 20-974/S-007
NDA 21-235/S-006

Eli Lilly and Company
Attention: Gregory T. Brophy, Ph.D.
Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285-2643

Dear Dr. Brophy:

We acknowledge receipt of your supplemental new drug applications dated January 31, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prozac and Sarafem (fluoxetine hydrochloride) pulvules (NDA 18-936), Prozac solution (NDA 20-101), Prozac tablets (NDA 20-974), and Prozac Delayed-Release Capsules (NDA 21-235).

These supplements, submitted as "Changes Being Effected" applications, provide for the following revisions to product labeling:

1. Changes to the **CONTRAINDICATIONS**, and **PRECAUTIONS-Drug Interactions** sections contraindicating the concomitant use of fluoxetine and pimozide.

2. The addition of the terms "erythema multiforme" to the *Postintroduction Reports* subsection.

We have completed the review of these supplemental applications, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted January 31, 2006), which incorporates the revisions listed. Accordingly, these supplemental applications are approved effective on the date of this letter.

Additionally, we note that you have incorporated the agreed upon revisions in regard to the juvenile rat study to the **Pediatric Use** section (lines 823-859 of your January 31, 2006 labeling) as outlined in our letter dated December 1, 2005. However. the statement below this (line 860) saying "See Animal Toxicology" should be removed. Likewise, the description of this juvenile rat study in the **Animal Toxicology** section (lines 1343-1358), which differs from the description of this same study in the pediatric section, should be removed. These changes should occur at the next printing, and they could be reported in the next annual report.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, call Renmeet Gujral, Pharm. D., Regulatory Project Manager, at 301-796-1080.

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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