DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-936/S-061/065
NDA 20-101/S-027
NDA 20-974/S-001

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:

Please refer to your supplemental new drug applications dated February 22, 2001 (NDA 18-936/S-065, 20-101/S-027, and 20-974/S-001) and July 26, 2000 (NDA 18-936/S-065), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prozac (fluoxetine HCl) capsules (NDA 18-936), Solution (NDA 20-101), and Tablets (NDA 20-974).

Reference is also made to Agency approvable letters dated December 20, 2001 (NDA 18-936/S-065, 20-101/S-027, and 20-974/S-001), and March 11, 2002 (NDA 18-936/S-061).

We acknowledge receipt of your submissions dated February 27, and May 6, 2002. Your submissions of February 27, and May 6, 2002 constituted a complete response to our December 20, 2001, and March 11, 2002 action letters.

Supplemental applications 18-936/S-065, 20-101/S-027, and 20-974/S-001 provide for the longer-term treatment of bulimia.

Supplemental application 18-936/S-061 provides for the treatment of panic disorder, with or without agoraphobia.

We note your agreement made in your May 6, 2002, submission to incorporate the proposed changes to labeling, verbatim, as requested in the Agency action letters dated December 20, 2001, and March 11, 2002. We additionally note your agreement in the May 6, 2002 submission to change the terminology from depression to major depressive disorder as requested in an Agency letter dated March 19, 2002.

We have completed the review of these supplemental applications, as amended, 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 agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDAs 18-936/S-061/S-065, 20-101/S-027, & 20-974/S-001." Approval of these submissions by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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 Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure

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

/s/

Russell Katz
7/29/02 09:26:57 AM