DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-235

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 new drug application (NDA) dated March 13, received March 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prozac Weekly (fluoxetine HCl) Delayed-Release 90 mg Capsules.

We acknowledge receipt of your submission dated January 15, 2001. Your submission of January 15, 2001 constituted a complete response to our January 8, 2001 action letter.

This new drug application provides for the use of Prozac Weekly (fluoxetine HCl) Delayed-Release 90 mg Capsules for the treatment of depression.

Reference is also made to a telephone conversation dated February 2, 2001, between Dr. Reed Tarwater, of your firm, and Mr. Paul David, of this Agency, in which Lilly agreed to the attached labeling for Prozac Weekly.

We have completed the review of this application, 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, the application is 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). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-235." Approval of this submission by FDA is not required before the labeling is used.

Additionally, we note your agreement, conveyed in your January 15, 2001 submission, to adopt a dissolution specification of Q=(b) in 45 minutes in buffer stage.

We additionally note your agreement to solely market this product in unit-of-use blister packaging.

The validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens must contain an assessment of the safety and effectiveness of the product in pediatric patients unless FDA waives or defers the requirement (63 *FR* 66632) [21 CFR 314.55]. The Agency has not made a determination if a health benefit would be gained by studying Prozac Weekly in pediatric patients for its approved indication. FDA is deferring submission of the pediatric assessments of safety and effectiveness that may be required under these regulations until March 1, 2002.

Please submit one market package of the drug product when it is available.

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 send one copy to the Division of Neuropharmacological Drug Products 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 Paul David, R.Ph., Regulatory Project Manager, at (301) 594-5530.

Sincerely,

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

Enclosure