DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 21-086

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

Dear Dr. Brophy:

Please refer to your new drug application (NDA) dated March 1, 1999, received March 2, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa Zydis (olanzapine) orally disintegrating tablets.

We acknowledge receipt of your submission dated January 27, 2000. Your submission of January 27, 2000 constituted a complete response to our December 23, 1999 action letter. We also acknowledge your electronic mail of March 21, 2000, providing draft labeling combining the Zyprexa tablet and Zyprexa Zydis orally disintegrating tablet labeling into a single package insert (attached).

This new drug application provides for the use of Zyprexa Zydis (olanzapine) orally disintegrating tablets for the management of the manifestations of psychotic disorders.

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 draft labeling (combined package insert submitted via electronic mail on March 21, 2000, and immediate container and carton labels submitted December 6, 1999). 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 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. For administrative purposes, this submission should be designated "FPL for approved NDA 21-086." Approval of this submission by FDA is not required before the labeling is used.

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.

You have been advised that the Pediatric Final Rule (63 FR 66632) requires that all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that your Proposed Pediatric Study Request was submitted to NDA 20-592 (Zyprexa tablets) on February 25, 2000 and received February 28, 2000. A formal Written Request will be forwarded to you under separate cover.

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 Steve Hardeman, R.Ph., Regulatory Project Manager, at (301) 594-5533.

Sincerely,

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

Enclosure