DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-592 / S-026

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 supplemental new drug application dated February 17, 2004, received February 18, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa (olanzapine) tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the container labels for 1000 count bottles of all approved strengths of Zyprexa tablets (2.5, 5, 7.5, 10, 15, and 20 mg). Specifically:

- The tamper resistant information "Do not use if Lilly inner seal is missing or broken" has been added to the container label.
- Zyprexa.com has been added in color shifting ink as an anti-counterfeiting measure to the container label.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 17, 2004.

If you have any questions, call CAPT Steven D. Hardeman, R.Ph., Acting Chief, Project Management Staff, at (301) 594-5525.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Acting 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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