



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-592 / S-020

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 November 22, 2002, received November 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa (olanzapine) 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg tablets.

We acknowledge receipt of your submissions of February 27, 2004, September 7, 2004, December 22, 2004, February 9, 2005, March 1, 2005, and May 5, 2005.

This "Changes Being Effected" supplement provides for changes to the bottle label for Zyprexa to assist in reducing the potential for medication errors involving Zyprexa and Zyrtec.

Specifically, the Zyprexa name is now ZyPREXA with the PREXA portion of the name back-highlighted in yellow. Tamper resistant information has been added to the label -- "Do not use if neck wrap or inner seal is broken."

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter.

Your risk management plan for reducing medication errors due to name confusion is also acceptable. We will continue to monitor the name confusion issue through your quarterly submissions of medication errors and your every six month submissions of risk management plan updates. Based on those evaluations, additional modifications to your risk management plan may be necessary.

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 Steven D. Hardeman, R.Ph., Senior Regulatory Project Manager, at (301) 594-5525.

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

**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
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