DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-253/S-026
NDA 20-592/S-042/S-043
NDA 21-086/S-022/S-023

Eli Lilly and Company
Attention: Catherine A. Melfi, Ph.D.
Scientific Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Melfi:

We acknowledge receipt of your supplemental new drug applications dated December 7, 2006 (21-253/S-026, 20-592/S-042, & 21-086/S-022), and January 5, 2007 (20-592/S-043 & 21-086/S-023) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the Zyprexa (olanzapine) tablets (NDA 20-592), Zyprexa Zydis (olanzapine) orally disintegrating tablets (NDA 21-086), and Zyprexa (olanzapine) Intramuscular Injection (NDA 21-253).

We additionally acknowledge receipt of your amendment dated December 19, 2006.

These supplemental new drug applications, submitted under "Changes Being Effected" provide for the following revisions to product labeling:

21-253/S-026, 20-592/S-042, & 21-086/S-022

1. In the **ADVERSE REACTIONS-Postintroduction Reports** section, the addition of the term neutropenia.
2. Deletion of the term "rarely" from the sentence regarding elevated cholesterol and triglyceride levels under the **ADVERSE REACTIONS-Postintroduction Reports** section.
3. Deletion of the 60 count bottle presentations from the **HOW SUPPLIED** section.

20-592/S-043 & 21-086/S-023

- In the **ADVERSE REACTIONS-Dose Dependency of Adverse Events in Short-term, Placebo-Controlled Trials** section, the addition of adverse event information based on an 8 week, randomized, double-blind, fixed-dose clinical trial that included 10 mg, 20 mg, and 40 mg doses of olanzapine.

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

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email LCDR Keith Kiedrow, Pharm.D., Regulatory Project Manager, at Keith.Kiedrow@HHS.FDA.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry 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/

Thomas Laughren
7/6/2007 09:43:45 AM