DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020592/S-052
NDA 021086/S-031
NDA 021253/S-037

SUPPLEMENT APPROVAL

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

Dear Dr. Brophy:

Please refer to your supplemental new drug applications dated and received on September 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyprexa (olanzapine) Tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, Zyprexa Zydis (olanzapine) Orally Disintegrating Tablets 5 mg, 10 mg, 15 mg, and 20 mg, and Zyprexa (olanzapine) IM Injection, 10 mg/vial.

We acknowledge receipt of your submissions dated September 18, 2009, October 6, 2009, and December 16, 2009.

These "Prior Approval" supplemental new drug applications provide for revisions to Section 5.15(Hyperprolactinemia).

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide). For administrative purposes, please designate this submission, **"SPL for approved supplement NDA 020592/S-052, 021086/S-031, & 021253/S-037021520/S-023."**

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

REPORTING REQUIREMENTS

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, call LCDR Keith Kiedrow, Regulatory Project Manager, at (301) 796-0240.

Sincerely,

{See appended electronic signature page}

Thomas P. Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures: Package Insert
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21253	SUPPL-37	ELI LILLY AND CO	ZYPREXA IM (OLANZAPINE) 10MG VIALS INJ
NDA-21086	SUPPL-31	ELI LILLY AND CO	ZYPREXA ZYDIS(OLANZAPINE)5/10/15/20/ MGTS
NDA-20592	SUPPL-52	ELI LILLY AND CO	ZYPREXA(OLANZAPINE) ORAL TABS 2.5MG/5MG/

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
01/27/2010