DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022173 / S-003, S-006

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Christine Phillips, PhD, RAC
Director, Global Regulatory Affairs, US
Lilly Corporate Center
Indianapolis, IN 46285

Dear Dr. Phillips:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received April 1, 2010 (S-003), and April 20, 2010 (S-006), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyprexa Relprevv (olanzapine) For Extended Release Injectable Suspension 210 mg, 300 mg, and 405 mg.

These "Prior Approval" supplemental new drug applications contain revisions to the following sections of the product labeling:

S-003:

WARNINGS AND PRECAUTIONS, 5.8 Weight Gain

S-006:

ADVERSE REACTIONS, 6.2 Vital Signs and Laboratory Studies
USE IN SPECIFIC POPULATIONS, 8.4 Pediatric Use

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.
The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, 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, email Keith Kiedrow, PharmD, Senior Regulatory Project Manager, at Keith.Kiedrow@FDA.HHS.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

ENCLOSURES:
Content of Labeling
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22173	SUPPL-6	ELI LILLY CO	ZYPREXA/ADHERA
NDA-22173	SUPPL-3	ELI LILLY CO	ZYPREXA/ADHERA

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
05/27/2010