DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022173 / S-004

SUPPLEMENT APPROVAL

Eli Lilly and Company
Attention: Matt Kuntz, RPh, MBA
Manager, Global Regulatory Affairs, US
Lilly Corporate Center
Indianapolis, IN 46285

Dear Mr. Kuntz:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 15, 2010, 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.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated May 10, 2010.

This "Prior Approval" supplemental new drug application provides for proposed modifications to the approved REMS for Zyprexa Relprevv.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Zyprexa Relprevv (olanzapine) was originally approved on December 11, 2009. The REMS consists of a Medication Guide, communication plan, elements to assure safe use, implementation system, and a timetable for submission of assessments of the REMS. Your proposed modification to the REMS consists of the following timetable for submission of assessments revised to align cutoff dates for REMS assessments and new drug application (NDA) and investigational new drug (IND) annual reports:

REMS assessment data cutoff date	REMS assessment due date
3/31/2010	5/30/2010
8/30/2010	10/29/2010
8/30/2011	10/29/2011
Annually on 8/30	Annually on 10/29

Your proposed modified REMS, submitted on January 15, 2010 and appended to this letter, is approved.

There are no changes to the REMS assessment plan described in our December 11, 2009 letter.

We remind you that the requirements for assessments of an approved REMS under section 505-1(g)(3) include, in section 505-1(g)(3)(A), an assessment of the extent to which the elements to assure safe use are meeting the goal or goals to mitigate a specific serious risk listed in the labeling of the drug, and whether the goal or goals or such elements should be modified.

Assessments of an approved REMS must include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

In addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

Prominently identify submissions containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission:

NDA 022173 REMS ASSESSMENT

NEW SUPPLEMENT FOR NDA 022173
PROPOSED REMS MODIFICATION
REMS ASSESSMENT

NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 022173
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)

If you do not submit electronically, please send 5 copies of REMS-related submissions.

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:
REMS

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22173	SUPPL-4	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
07/08/2010