



NDA 022173 S-008/S-010/S-014

## SUPPLEMENT APPROVAL

Eli Lilly and Company  
Attention: Ashraff Rampersaud, M.S. PMP  
Manager, Global Regulatory Affairs, US  
Lilly Corporate Center  
Indianapolis, IN 46285

Dear Mr. Rampersaud:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received May 28, 2010 (S-008), October 29, 2010 (S-010), and October 28, 2011 (S-014), 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 vials.

These "Prior Approval" REMS modification supplemental new drug applications provide for updates to various REMS forms and accompanying materials as well as updates to the Medication Guide.

The REMS for Zyprexa Relprevv was originally approved on December 11, 2009, and a REMS modification was approved on July 8, 2010. 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.

We have completed our review of these supplemental applications. 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, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide, REMS), with the addition of any labeling changes in pending "Changes Being Effectuated" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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

### **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 Keith Kiedrow, Pharm.D., Regulatory Project Manager, at (301) 796-1924.

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(S):

Content of Labeling  
Medication Guide  
REMS  
REMS Program Forms

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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THOMAS P LAUGHREN  
08/03/2012