



NDA 020592 / S-053, S-055

NDA 021086 / S-032, S-034

NDA 021253 / S-039, S-043

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 October 23, 2009 and received October 26, 2009 (S-053, S-032, and S-039) and dated and received April 1, 2010 (S-055, S-034, S-043), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Zyprexa (olanzapine) Tablets (NDA 020592), 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, Zyprexa Zydys (olanzapine) Orally Disintegrating Tablets (NDA 021086), 5 mg, 10 mg, 15 mg, and 20 mg, and Zyprexa (olanzapine) IM Injection (NDA 021253), 10 mg/vial.

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

S-052, S-032, S-39:

ADVERSE REACTIONS, 6.2 Vital Signs and Laboratory Studies

S-055, S-034, S-043:

WARNINGS AND PRECAUTIONS, 5.6 Weight Gain

WARNINGS AND PRECAUTIONS, 5.8 Orthostatic Hypotension

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 Effectuated" (CBE)

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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, Pharm.D., 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-21253	SUPPL-43	ELI LILLY AND CO	ZYPREXA IM (OLANZAPINE) 10MG VIALS INJ
NDA-21253	SUPPL-39	ELI LILLY AND CO	ZYPREXA IM (OLANZAPINE) 10MG VIALS INJ
NDA-21086	SUPPL-34	ELI LILLY AND CO	ZYPREXA ZYDIS(OLANZAPINE)5/10/15/20/ MGTS
NDA-21086	SUPPL-32	ELI LILLY AND CO	ZYPREXA ZYDIS(OLANZAPINE)5/10/15/20/ MGTS
NDA-20592	SUPPL-55	ELI LILLY AND CO	ZYPREXA(OLANZAPINE) ORAL TABS 2.5MG/5MG/
NDA-20592	SUPPL-53	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
05/27/2010