



NDA 20-592 / S-027 / S-032

NDA 21-086 / S-009 / S-013

NDA 21-253 / S-004 / S-012

Eli Lilly and Company
Attention: Robin Pitts Wojcieszek, R.Ph.
Associate Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, Indiana 16285

Dear Ms. Wojcieszek:

Please refer to your supplemental new drug applications dated May 9, 2005, received May 10, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa (olanzapine) tablets and orally disintegrating tablets, and Zyprexa IntraMuscular (olanzapine for injection).

Refer also to your supplements dated May 20, 2004, received May 21, 2004, for the Zyprexa products.

Your submissions of October 7, 2005, constituted a complete response to our action letter of August 17, 2005.

The May 9, 2005 "Changes Being Effectuated" supplemental new drug applications provide for a Boxed Warning and Bolded Warning section of the labeling concerning increased mortality in elderly patients with dementia-related psychosis.

The May 20, 2004 "Changes Being Effectuated" supplemental new drug applications provide for revised labeling based on a review of integrated safety data from seven clinical studies of olanzapine in elderly patients with dementia. Revised labeling included the addition of a Warning describing increased mortality in olanzapine-treated patients compared with placebo-treated patients and updates the Dysphagia, Use in Patients with concomitant Illness, and Geriatric Use sub-sections under Precautions.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 7, 2005 (attached).

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

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If you have any questions, call LT 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

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/s/

Thomas Laughren
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