



NDA 21-253 / S-016
NDA 21-086 / S-016
NDA 20-592 / S-035

Eli Lilly and Company
Attention: Robin Pitts Wojcieszek, R.Ph.
Associate Director, U.S. Regulatory Affairs
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Ms. Wojcieszek:

Please refer to your supplemental new drug applications dated September 30, 2005, received October 3, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa (olanzapine) tablets, Zyprexa Zydis (olanzapine) orally disintegrating tablets, and Zyprexa IntraMuscular (olanzapine) for injection.

These “Changes Being Effected” supplemental new drug applications provide for:

1. Changes to the Zyprexa IntraMuscular carton and vial label revising the strength to read “10mg/vial,” and including the following statement on the carton side panel describing the resultant strength once the product is reconstituted: “Upon reconstitution with 2.1 mL of Sterile Water for Injection, each mL will contain 5 mg of olanzapine.”
2. Removal of all trailing zeros from the Zyprexa package inserts.

We have completed our review of these supplemental new drug applications and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on September 30, 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.

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

**This is a representation of an electronic record that was signed electronically and
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/s/

Thomas Laughren
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