



NDA 20-592 / S-019

Eli Lilly and Co., Inc.  
Attention: Gregory T. Brophy, Ph.D.  
Lilly Corporate Center  
Indianapolis, Indiana 46285  
USA

Dear Dr. Brophy:

Please refer to your supplemental new drug application (NDA) dated November 20, 2002, received November 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zyprexa (olanzapine) Tablets, 2.5, 5, 7.5, 10, 15, and 20 mg. This supplemental NDA provides for the use of olanzapine in the long-term treatment of bipolar I disorder.

We also acknowledge receipt of your amendments dated November 4, 2003 and November 13, 2003. Your submission of November 13, 2003 constituted a complete response to our September 22, 2003 action letter.

**Application approved.** We have completed the review of this application as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, per our discussions of January 13, 2004.

**Final Printed Labeling.** The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Please submit the FPL electronically, according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FPL for approved supplement NDA 20-592/S-019”. Approval of this submission by FDA is not required before the labeling is used.

**Waiver of Requirement for Pediatric Studies.** All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for the use of olanzapine in the long-term treatment of bipolar I disorder.

**No Postmarketing Commitments Required.** We note that there are no postmarketing commitments for this supplemental application.

**Promotional Materials.** In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising and Communications (DDMAC), HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

**Dear Healthcare Professional Letters.** If you issue a letter communicating important information about this drug product (i.e., a “Dear Healthcare Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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, please contact Doris J. Bates, Ph.D., Regulatory Project Manager, at 301-594-2850, or via e-mail at [batesd@cderr.fda.gov](mailto:batesd@cderr.fda.gov).

Sincerely,

*(See appended electronic signature page)*

Russell Katz, M.D.  
Director  
Division of Neuropharmacological Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

Enclosure (Agreed-Upon Labeling) [The electronic signature page will follow the labeling.]

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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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Russell Katz

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