DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 090798

Apotex Corp.
U.S. Agent for Apotex Inc.
Attention: Kiran Krishnan
Director, North American Regulatory Affairs
2400 North Commerce Parkway, Suite 400
Weston, Florida 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.

Reference is also made to your amendments dated October 28, and December 23, 2011; and February 7, and March 13, 2012. We also reference your patent amendments dated February 13, 2009 and October 28, 2011.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zyprexa Tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, of Eli Lilly and Company. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The RLD upon which you have based your ANDA, Zyprexa Tablets, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, of Eli Lilly and Company (Eli Lilly), is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations(the "Orange Book"):

U.S. Patent Number	Expiration Date
5,229,382 (the '382 patent)	October 23, 2011*
5,605,897 (the '897 patent)	August 25, 2014*
5,627,178 (the '178 patent)	October 23, 2011*
5,736,541 (the '541 patent)	September 24, 2015*
5,817,655 (the '655 patent)	October 23, 2011*
5,817,656 (the '656 patent)	October 23, 2011*
5,817,657 (the '657 patent)	October 23, 2011*
5,919,485 (the ’485 patent)	September 24, 2015*
6,251,895 (the ‘895 patent)	March 23, 2018*
6,960,577 (the ‘577 patent)	November 1, 2017

* with pediatric exclusivity

Your ANDA contains a Paragraph III Certification to the ‘382, ‘178, ‘655, ‘656, and ‘657 patents under section 505(j)(2)(A)(vii)(III) of the Act. This certification states that Apotex Inc. (Apotex) will not market your Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, prior to the expiration of the patents. The agency recognizes the patents have expired, no longer precluding the agency from approving your application.

With respect to the '541, '485, and '895 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg, under this ANDA. You have notified the agency that Apotex complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Apotex within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).

With respect to the ‘897 and ‘577 patents, your ANDA contains statements under section 505(j)(2)(A)(viii) of the Act that these are method of use patents that do not claim any indication for which you are seeking approval under your ANDA.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Please note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Office of Prescription Drug Promotion with a completed Form FDA 2253 at the time of their initial use.

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 in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). 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/U CM072392.pdf. The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ROBERT L WEST

04/23/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.