DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 077561

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) received on February 7, 2005, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base).

Reference is also made to your amendments dated June 16, 2005; January 3, June 30, and August 18, 2006; June 6, and December 17, 2007; April 28, July 3, July 24, and July 31, 2009; August 4, 2010; and August 25, October 4, and December 13, 2011. We also acknowledge receipt of your correspondences dated April 15, and July 8, 2005; and June 7, 2007 addressing the patent and exclusivity issues associated with this ANDA.

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 Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Geodon Capsules 20 mg (base), 40 mg (base), 60 mg (base) and 80 mg (base), respectively, of Pfizer Inc. (Pfizer). 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 your ANDA is based, Pfizer's Geodon Capsules, is subject to periods of patent protection. The following unexpired patents and their expiration dates are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for this drug product:

U.S. Patent Number	Expiration Date
5,312,925 (the '925 patent)	September 1, 2012
6,150,366 (the '366 patent)	May 27, 2019
6,245,766 (the '766 patent)	December 18, 2018

With respect to the '925 and '366 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base), under this ANDA. You have notified the agency that Apotex Corp. (Apotex) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against Apotex.

With respect to the '766 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that it does not claim any indication for which you are seeking approval under your ANDA.

Apotex was one of the first applicants to submit a substantially complete ANDA with paragraph IV certifications to the '925 and '366 patents. As a first applicant, therefore, Apotex may be eligible for 180 days of generic drug exclusivity for Ziprasidone Hydrochloride Capsules, 20 mg (base), 40 mg (base), 60 mg (base), and 80 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing by any first applicant. The agency notes that Apotex failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of Apotex's eligibility for 180-day generic drug exclusivity. Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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 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
03/02/2012
Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.