DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 091388

Aurobindo Pharma USA, Inc.
U.S. Agent for Aurobindo Pharma Limited
Attention: Blessy Johns
2400 Route 130 North
Dayton, NJ 08810

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 31, 2009, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Quetiapine Fumarate Tablets, 25 mg (base), 50 mg (base), 100 mg (base), 150 mg (base), 200 mg (base), 300 mg (base), and 400 mg (base).

Reference is also made to your amendments dated October 27, 2009; March 7, April 8, May 10, May 27, July 15, August 12, and November 16, 2011; and January 17, and February 21, 2012.

We note that one of the drug products upon which you have based this ANDA, AstraZeneca L.P.'s Seroquel Tablets 150 mg (base), is no longer being marketed in the U.S., and is currently listed in the discontinued section of the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). Reference is made to the Federal Register notice dated January 25, 2008 (Volume 73, No. 17) in which the agency announced its determination that Seroquel Tablets 25 mg (base) were not withdrawn from sale for reasons of safety or effectiveness. This determination allows the agency to approve ANDAs for the discontinued drug product.

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 Quetiapine Fumarate Tablets, 25 mg (base), 50 mg (base), 100 mg (base), 150 mg (base), 200 mg (base), 300 mg

(base), and 400 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug product (RLD), Seroquel Tablets, 25 mg (base), 50 mg (base), 100 mg (base), 150 mg (base), 200 mg (base), 300 mg (base), and 400 mg (base), respectively, of AstraZeneca LP. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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.

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

03/27/2012

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