ANDA 78-787

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-8474

FAX TRANSMISSION COVER SHEET

DATE: January 31, 2008

TO: APPLICANT: Aurobindo Pharma Ltd. TEL: 732-839-9406

ATTN: Prasada Kambham FAX: 732-355-9940

FROM: Lisa Kwok PROJECT MANAGER: 240-276-8492

TOTAL NUMBER OF PAGES: 4
(EXCLUDING COVER SHEET)

Special Instructions:

Congratulations!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-787

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 30, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Gabapentin Capsules, 100 mg, 300 mg and 400 mg.

Reference is also made to your amendments dated July 23, and August 4, 2007. We also acknowledge receipt of your correspondence dated May 29, and July 5, 2007, addressing the patent 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 Gabapentin Capsules, 100 mg, 300 mg and 400 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Neurontin Capsules, 100 mg, 300 mg and 400 mg, respectively, of Pfizer Pharmaceuticals, Ltd. (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 you have based your ANDA, Pfizer's Neurontin Capsules, 100 mg, 300 mg and 400 mg, is subject to periods of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent Nos. 4,894,476 (the '476 patent) and 6,054,482 (the '482 patent) are scheduled to expire on November 2, 2008, and October 25, 2017, respectively, (with pediatric extensions).

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Gabapentin Capsules, 100 mg, 300 mg and 400 mg, under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action was brought against Aurobindo Pharma Limited (Aurobindo) for infringement of one or both of the patents that were the subjects of the paragraph IV certifications. You notified the agency that Aurobindo complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement of either of these patents was brought against Aurobindo within the statutory 45-day period, which action would have resulted in a 30-month stay of approval under section 505(j)(5)(B)(iii) of the Act.

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
Division of Drug Marketing, Advertising, and Communications
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 Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(See appended electronic signature page)

Gary Buehler
Director
Office of Generic Drugs
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
1/31/2008 01:55:27 PM
for Gary Buehler