



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-539

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated September 30, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base), and 24 mg (base).

Reference is also made to your amendments dated January 25, April 3, June 30, and July 19, 2007. We also acknowledge receipt of your correspondence dated February 2, and February 27, 2007, pertaining to 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 Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base), and 24 mg (base), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Zofran Tablets, 4 mg (base), 8 mg (base), and 24 mg (base), respectively, of GlaxoSmithKline (GSK). 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, GSK's Zofran Tablets, is subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S.

Patent No. 5,344,658 (the '658 patent), is scheduled to expire (with pediatric exclusivity added) on March 6, 2012.

Your ANDA contains a paragraph IV certification to the '658 patent under section 505(j)(2)(A)(vii)(IV) of the Act stating that this patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base), and 24 mg (base), 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 the listed '658 patent. You have notified the agency that Aurobindo complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement 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).

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/

Gary Buehler

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