ANDA 78-152

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 301-594-0180

FAX TRANSMISSION COVER SHEET

APPLICANT: TEL: 201-684-8017

ATTN: William McIntyre FAX: 201-831-0080

FROM: Theresa Liu PROJECT MANAGER: (301) 827-5791

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated January 27, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Ondansetron Orally Disintegrating Tablets, 4 mg and 8 mg.

We are pleased to inform you that this application is APPROVED!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 78-152

Glenmark Pharmaceuticals Inc., USA
U.S. Agent for: Glenmark Pharmaceuticals Limited
Attention: William R. McIntyre, Ph.D.
Executive Vice President, Regulatory Affairs
750 Corporate Drive
Mahwah, NJ 07430

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated January 27, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 mg.

Reference is also made to your amendments dated June 26, and December 12, 2006; and January 4, March 1, April 5, May 9, and June 7, 2007. We also acknowledge receipt of your correspondence dated March 24, 2006, and June 20, 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 provided for 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 Orally Disintegrating Tablets USP, 4 mg and 8 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Zofran ODT Tablets 4 mg and 8 mg, respectively, of GlaxoSmithKline. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Zofran, ODT 4 mg and 8 mg of GlaxoSmithKline (GSK), 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. 5,955,488 (the '488 patent) and 6,063,802 (the '802 patent) are each scheduled to expire (with pediatric exclusivity added) on May 14, 2016.

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ondansetron Orally Disintegrating Tablets USP, 4 mg and 8 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 Glenmark Pharmaceuticals Limited (Glenmark) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against Glenmark prior to the expiration of 45 days from the date the notice you provided under section 505 (j)(2)(B)(i) was received by the NDA/patent holder(s). You have notified the agency that Glenmark complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Glenmark within the statutory 45-day period, which action would have resulted in a 30-month stay under section 505(j)(5)(B)(iii).[1]

Furthermore, the 180-day generic drug exclusivity period for this drug product awarded by the agency to Kali Laboratories has expired.

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 application 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

[1]Because information on the '488 and '802 patents was/were submitted to FDA before August 18, 2003, this is reference to section 505(j)(5)(B)(iii) is to that section of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

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
6/27/2007 12:09:11 PM
for Gary Buehler