



ANDA 76-183

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Director-Global Regulatory Affairs & Compliance
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 4, 2001, 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 October 3, 2001; April 22, 2002; August 20, 2003; December 14, 2004; July 20, August 29, December 2, December 22, 2005; and April 10, April 24, November 28, December 7 (2 amendments), December 8, December 14, and December 18, 2006. We also acknowledge receipt of your correspondences dated September 6, 2001, May 7, June 15, and June 22, 2004; and May 17, June 15 and November 20, 2006.

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, 4 mg (base), 8 mg (base) and 24 mg (base), is currently 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. 4,753,789 (the '789 patent) and 5,344,658 (the '658 patent) are scheduled to expire (with pediatric exclusivity added) on December 24, 2006, and March 6, 2012, respectively. With respect to the '658 and '789 patents, your ANDA contains paragraph IV certifications 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 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 action was brought against Dr. Reddy's Laboratories Limited (DRL) for infringement of one or more of the patents that were the subjects of paragraph IV certifications. You notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act and litigation for infringement of the '789 patent was brought against DRL in the United States District Court for the District of New Jersey (Glaxo Group Limited and SmithKline Beecham Corporation v. Dr. Reddy's Laboratories, Ltd. and Reddy-Cheminor, Inc., Civil Action No. 01-4066). You notified us on June 15, 2006, that DRL and Glaxo Group and SmithKline Beecham entered a settlement agreement with respect to this litigation. You have also stated that no litigation was filed against DRL with respect to the '658 patent.

As required by the settlement agreement, DRL amended its certification with respect to the '789 patent from a paragraph IV to a paragraph III under section 505(j)(2)(A)(vii)(III) of the Act. This certification states that DRL will not market its Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base) and 24 mg (base), prior to the expiration of the patent. The patent having expired, the agency recognizes that your ANDA is now eligible for approval.

With respect to 180-day generic drug exclusivity, we note that DRL was the first ANDA applicant for Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base) and 24 mg (base) to submit a substantially complete ANDA with a paragraph IV certification to the '789 and '658 patents. Therefore, with this approval, DRL is eligible for 180 days of generic drug exclusivity for Ondansetron Hydrochloride Tablets, 4 mg (base), 8 mg (base) and 24 mg (base). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, will begin to run from the earlier of the commercial marketing or court decision dates

identified in section 505(j)(5)(B)(iv).¹ Please submit correspondence to this ANDA informing the agency of the date the exclusivity begins to run.

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

¹Because your ANDA was filed before the date of enactment of the Medicare Prescription Drug, Improvement and Modernization Act (MMA) (Public Law 108-173) on December 8, 2003, this reference to the 180-day exclusivity provision is to the section of the Act as in effect prior to December 8, 2003. See MMA § 1102(b)(1).

**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
12/26/2006 08:19:24 AM
for Gary Buehler