DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-559

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

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated December 6, 2002, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Ondansetron Hydrochloride Tablets, 16 mg (base).

Reference is also made to your amendments dated June 13, August 29, December 2, and December 22, 2005; and January 19, April 4, November 29, and December 14, 2006. We also acknowledge receipt of your correspondences dated September 8, 2003; May 7, June 15, June 22, 2004; and June 15, 2006, addressing the patent issues associated with this ANDA.

Reference is also made to the ANDA suitability petition submitted under section 505(j)(2)(c) of the Act and approved on April 12, 2002. The reference listed drug (RLD), Zofran Tablets of GlaxoSmithKline (GSK), only has approved labeling for the 4 mg (base), 8 mg (base), and 24 mg (base) tablet strengths. The approved petition allows the agency to accept an ANDA for an additional tablet strength, Ondansetron Hydrochloride Tablets, 16 mg (base).

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 that your Ondansetron Hydrochloride Tablets, 16 mg (base) can be expected to have the same therapeutic effect as that of an equivalent dose of the reference listed drug product upon which the agency relied as the basis of safety and effectiveness. 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, 16 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, 16 mg (base), prior to the expiration of the '789 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, 16 mg (base) to submit a substantially complete ANDA with a paragraph IV certification to the '658 patent. Therefore, with this approval, DRL is eligible for 180 days of generic drug exclusivity for Ondansetron Hydrochloride Tablets,

16 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

[1]Because 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 08:57:49 AM
for Gary Buehler