ANDA 78-490

OFFICE OF GENERIC DRUGS

Food and Drug Administration
HFD-600, Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773
Fax: 240-276-9327

FAX TRANSMISSION COVER SHEET

APPLICANT: Dr. Reddy's Laboratories Inc., U.S. Agent for Dr. Reddy's Laboratories Limited

TEL: 908-203-4937

FAX: 908-203-4980

ATTN: Kumara Sekar, Ph.D.

FDA CONTACT PHONE: (240) 276-8555

FROM: Theresa Liu

Dear Sir:

This facsimile is in reference to your abbreviated new drug application dated September 13, 2006 and December 20, 2006, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act for Omeprazole Delayed Release Capsules USP, 40 mg, 20 mg, and 10 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 78-490

Dr. Reddy's Laboratories Inc.
U.S. Agent for: Dr. Reddy's Laboratories, Limited
Attention: Kumara Sekar, Ph.D.
Senior 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 September 13, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Omeprazole Delayed-release Capsules USP, 40 mg.

Reference is made to the tentative approval letter issued by this office on May 23, 2008, and to your amendments dated May 8, and June 25, 2007; and February 18, and March 5, 2009.

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 Omeprazole Delayed-release Capsules USP, 40 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Prilosec Delayed-release Capsules, 40 mg of AstraZeneca LP.

Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA. [redacted]

The RLD upon which you have based your ANDA, AstraZeneca's Prilosec Capsules, 40 mg, is subject to periods of patent protection. The following patents and expiration dates (with pediatric exclusivity added) are currently listed in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent Number	Expiration Date
6,147,103 (the '103 patent)	April 9, 2019
6,150,380 (the '380 patent)	May 10, 2019
6,166,213 (the '213 patent)	April 9, 2019
6,191,148 (the '148 patent)	April 9, 2019

With respect to each of these patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Omeprazole Delayed-release Capsules USP, 40 mg, under this ANDA. You have notified the agency that Dr. Reddy's Laboratories Limited (DRL) complied with the requirements of section 505(j)(2)(B) of the Act, and that no action for infringement was brought against DRL 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.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

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.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as ***"Miscellaneous Correspondence - SPL for Approved ANDA 78-490".***

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
4/17/2009 02:25:37 PM
Deputy Director, for Gary Buehler