DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 75-576

Dr. Reddy's Laboratories Inc.
US 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 February 3, 1999, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Omeprazole Delayed-release Capsules USP, 10 mg, 20 mg, and 40 mg.

Reference is also made to our tentative approval letter dated February 13, 2006, and to your amendments dated June 4, August 16, September 10, and October 3, 2007.

The reference listed drug (RLD) upon which you have based your ANDA, AstraZeneca's Prilosec Delayed-release Capsules, 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") for this drug product:

U.S. Patent Number	Expiration Date
4,786,505 (the '505 patent)	October 20, 2007
4,853,230 (the '230 patent)	October 20, 2007
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

Your ANDA contains paragraph IV certifications to the '103, '380, '213 and '148 patents 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, 10 mg, 20 mg and 40 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 Dr. Reddy's Laboratories, Inc. (DRL) for infringement of one or more of these 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 no action for patent infringement involving the '103, '380, '213 or '148 patents 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) of the Act.

With respect to the '505 and '230 patents, your ANDA contains paragraph III certifications under section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this drug product prior to the expiration of these patents on October 20, 2007.

I. Approval of Omeprazole Delayed-release Capsules USP, 10 mg and 20 mg.

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, approval is granted for your Omeprazole Delayed-release Capsules USP, 10 mg and 20 mg. The Division of Bioequivalence has determined your Omeprazole Delayed-release Capsules USP, 10 mg and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug RLD, Prilosec Delayed-release Capsules of AstraZeneca LP. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

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.

II. Tentative Approval of Omeprazole Delayed-release Capsules USP, 40 mg.

Your Omeprazole Delayed-release Capsules USP, 40 mg, remains tentatively approved because of another applicant's eligibility for 180-day generic drug exclusivity. An ANDA from that applicant for the 40 mg strength containing a paragraph IV certification was submitted prior to the submission of your ANDA. Your Omeprazole Delayed-release Capsules USP, 40 mg, will be eligible for final approval upon the expiration of the other applicant's 180-day generic drug exclusivity (i.e., 180 days after the date the agency receives notice of the first commercial marketing of the 40 mg strength under the previous ANDA), or until that applicant's eligibility for 180-day generic drug exclusivity for Omeprazole Delayed-release Capsules USP, 40 mg has been resolved.

Our decision to maintain tentative approval of your Omeprazole Delayed-release Capsules USP, 40 mg, is based upon information currently available to the agency (i.e., data in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product). This decision is subject to change on the basis of new information that may come to our attention.

To reactivate this ANDA to provide for final approval of your Omeprazole Delayed-release Capsules USP, 40 mg, you must submit a "Supplemental Application – Expedited Review Requested." This supplement should be submitted for prior approval approximately 90 days prior to the date you believe that your 40 mg strength will be eligible for final approval. The supplement should include a detailed explanation of why and when you believe final approval should be granted. It should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This supplement should be submitted even if no changes have been made to the application since the date of this tentative approval. Significant changes, as well as an update of the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the supplemental application will be granted. We request that you categorize the changes as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt.

In addition to the supplemental application requested above, the Agency may request at any time prior to the date of final approval that you submit an additional supplement containing the requested information. Failure to submit either or, if requested, both supplements may result in the rescission of the tentative approval status of your ANDA insofar as the 40 mg strength, or may result in a delay in the issuance of the final approval letter.

Any significant changes in the conditions outlined in this ANDA as well as changes in the status of the manufacturing and testing facilities' compliance with cGMPs are subject to agency review before final approval of the supplemental application will be made. Such changes should be categorized as representing either "major" or "minor" changes, and they will be reviewed according to OGD policy in effect at the time of receipt. The submission of multiple supplements prior to final approval may also result in a delay in the issuance of the final approval letter.

Please note that under section 505 of the Act, your Omeprazole Delayed-release Capsules USP, 40 mg, may not be marketed without final agency approval. The introduction or delivery for introduction into interstate commerce of your 40 mg strength before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, your 40 mg strength will not be deemed approved for marketing under section 505 of the Act, and will not be listed in the "Orange Book."

For further information on the status of this ANDA, or prior to submitting additional amendments, please contact Theresa Liu, Project Manager, at 301-827-5791.

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
10/22/2007 03:51:33 PM
for Gary Buehler