CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 078997

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078997

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Ltd.
Attention: Kimberly Ernst
Director, Global Regulatory Affairs
200 Somerset Corporate Blvd., 7th Floor
Bridgewater, NJ 0880

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) received on May 16, 2007, and submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly).

Reference is made to your amendments dated December 22, 2008; January 6, and January 30, 2009; January 6, May 20, August 19, December 9, and December 20, 2010; May 10, and July 26, 2011; and February 14, February 16, and March 19, 2012.

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 Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly) to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Boniva Tablets, 150 mg (base), of Hoffman-La Roche Inc. (HLR). 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, HLR's Boniva Tablets, is subject to periods of patent protection. The following unexpired patents and their expiration dates 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
6,294,196 (the '196 patent)	October 7, 2019
7,192,938 (the '938 patent)	May 6, 2023
7,410,957 (the '957 patent)	May 6, 2023
7,718,634 (the '634 patent)	May 6, 2023

With respect to each of these patents, your ANDA contains a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Ibandronate Sodium Tablets, 150 mg, under this ANDA. You notified the agency that Dr. Reddy's Laboratories Ltd. (DRL) complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '196 and '938 patents was brought against DRL within the statutory 45-day period in the United States District Court for the District of New Jersey [Hoffmann-La Roche Inc. v. Dr. Reddy's Laboratories Ltd and Dr. Reddy's Laboratories Inc., Civil Action No. 07-4516(SRC)(MAS)]. You have notified the agency that the case for infringement of the '196 and '938 patents has been dismissed. Although litigation with respect to the '957 and '634 patents remains ongoing, the 30-month period identified in section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your ANDA, has expired.

With respect to 180-day generic drug exclusivity, we note that DRL was one of the first ANDA applicants for Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly), to submit a substantially complete ANDA with a paragraph IV certification. Therefore, with this approval, DRL may be eligible for 180 days of generic drug exclusivity for Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly). This exclusivity, which is provided for under section 505(j)(5)(B)(iv) of the Act, would begin to run from the date of the commercial marketing by a first applicant identified in section 505(j)(5)(B)(iv). The agency notes that DRL failed to obtain tentative approval of this ANDA within 30 months after the date on which the ANDA was filed. See section 505(j)(5)(D)(i)(IV) (forfeiture of exclusivity for failure to obtain tentative approval). The agency is not, however, making a formal determination at this time of DRL's eligibility for 180-day generic drug exclusivity. It will do so only if an application submitted by an applicant other than a first applicant becomes eligible for full approval within 180 days after a first applicant begins commercial marketing of Ibandronate Sodium Tablets, 150 mg (base) (Once-Monthly). Please submit correspondence to this ANDA informing the agency of the date commercial marketing begins.

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
Office of Prescription Drug Promotion
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.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/U_CM072392.pdf

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

{See appended electronic signature page}

Keith Webber, Ph.D.
Deputy Director
Office of Pharmaceutical Science
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

04/30/2012

Deputy Director, Office of Generic Drugs
for Keith Webber, Ph.D.