DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 202194

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kimberly Ernst
Director, Global Regulatory Affairs
200 Somerset Corporate Boulevard, 7th Floor
Bridgewater, NJ 08807-2862

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 9, 2010, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC).

Reference is also made to your amendments dated October 22 and November 3, 2010; January 17, May 3, December 2 (2), and December 13, 2011; and January 25, February 9, February 20, and March 5, 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 over-the-counter (OTC) 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 Lansoprazole Delayed-Release Capsules USP, 15 mg (OTC) to be bioequivalent to the reference listed drug product (RLD), Prevacid 24 HR Delayed-release Capsules, 15 mg, of Novartis Consumer Health, Inc.

Your dissolution testing should be incorporated into the stability and quality control program using the same USP method proposed in your application. The "interim" dissolution specifications are as follows:

Dissolution Testing should be conducted using the USP method: 500 mL of 0.1 N HCl at the acid stage in one hour followed by 900 mL of pH 6.8 Phosphate Buffer with 5 mM SDS at 37°C ± 0.5°C using USP apparatus II at 75 rpm). The product should meet the following "interim" dissolution specifications:

Acid Stage: Not more than (b)(4) of the labeled amount of Lansoprazole is dissolved in 60 minutes, and

Buffer Stage: Not less than (b)(4) (Q) of the labeled amount Of Lansoprazole is dissolved in 60 minutes.

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data from the first three production size batches. These data should be submitted as a "Special Supplement – Changes Being Effected" when there are no revisions to be made to the "interim" specifications, or if the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

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

05/18/2012

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