DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 078367

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 Boulevard, 7th Floor
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg.

Reference is also made to your amendments dated January 24, September 5, November 7, and December 20, 2007; January 28, March 17, and December 23, 2008; March 9, March 13, March 17, and April 3, 2009; and March 19, and March 31, 2010.

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 Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clarinex Reditabs, 2.5 mg and 5 mg, respectively, of Schering Corporation (Schering). 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, Schering’s Clarinex Reditabs, is subject to periods of patent protection. The following patents and their 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
5,178,878 (the '878 patent)	July 12, 2010
5,607,697 (the '697 patent)	December 7, 2015
6,100,274 (the '274 patent)	January 7, 2020
7,211,582 (the '582 patent)	June 30, 2015
7,214,683 (the '683 patent)	June 30, 2015
7,214,684 (the '684 patent)	June 30, 2015
7,618,649 (the '649 patent)	June 19, 2021

With respect to the '582 patent, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act that this is a method of use patent, and that it does not claim any indication for which you are seeking approval.

With respect to the ‘878, ‘697, ‘274, ‘683, ‘684, and ‘649 patents, your ANDA contains paragraph IV certifications under section 505(j)(2)(A)(vii)(IV) of the Act stating that each of these patents is invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Desloratadine Orally Disintegrating Tablets, 2.5 mg and 5 mg, under this ANDA. Of the patents listed above, only the ‘697 and ‘274 patents were listed in the Orange Book when your ANDA was received; your paragraph IV certifications to the other patents were submitted in amendments to your 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 Limited (DRL) for infringement of one or more of the patents that were the subjects of the paragraph IV certifications, excluding those submitted in an amendment. You notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation for infringement of the '274 patent (as well as the '683 and '684 patents), was brought against DRL in the United States District Court for the District of New Jersey [Schering Corporation v. Dr. Reddy's Laboratories Ltd, Civil Action Nos. 06-4715(MLC) and 07-5001]. You have further notified the agency that the case involving the ‘274 patent was dismissed. You have also notified the agency that no action for infringement of the ‘697 patent was brought against DRL within the statutory 45-day period.

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.

Please 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.

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