



ANDA 078366

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 June 21, 2006, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Desloratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/240 mg (24 Hour Formulation).

Reference is also made to your amendments dated March 12, July 2, July 18, October 2, and November 14, 2007; July 7, 2008; April 1 (2), and August 10, 2009; November 29, 2010; and January 25, and March 29, 2011. We also acknowledge receipt of your correspondence dated December 22, 2006; November 14, 2007; and March 28, and April 12, 2011 addressing the patent issues associated with this ANDA.

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 and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg and 240 mg (24 Hour Formulation), to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug (RLD), Clarinex-D 24 Hour Extended-release Tablets, of Schering Corp. (Schering).

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

For Desloratadine:

Apparatus: USP Apparatus II (Paddle)
Speed: 50 rpm
Medium: 0.1 N HCl at 37°C
Volume 1000 mL

Specification: NLT (b)(4) (Q) of Desloratadine in the dosage form (b)(4) dissolved within 30 minutes.

For Pseudoephedrine:

Acid Stage (Acid Resistance Test)
Apparatus: USP Apparatus II (Paddle)
Speed: 50 rpm
Medium: 0.1 N HCl at 37°C
Volume: 1000 mL

Specification: Pseudoephedrine (b)(4) is dissolved in 1 hour.

Buffer Stage (Drug Release Test)

Apparatus: USP Apparatus II (Paddle)
Speed: 50 rpm
Medium: 0.1 M potassium phosphate buffer, pH 7.5, at 37°C
Volume: 1000 mL

Specifications:

<u>Time (hours)</u>	<u>Percent Dissolved</u>
1	(b)(4)
2	
4	
8	
16	

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" if 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.

The reference listed drug (RLD) upon which you have based your ANDA, Clarinex-D 24 Hour Extended-release Tablets, 5 mg/240 mg of Schering Corp, is subject to periods of patent protection. The following 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>U.S. Patent Number</u>	<u>Expiration Date</u>
6,100,274 (the '274 patent)	January 7, 2020*
6,979,463 (the '463 patent)	March 28, 2022
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*
7,820,199 (the '199 patent)	September 28, 2022*

*pediatric exclusivity added

Your ANDA contains paragraph IV certifications to each of these patents under section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents are invalid, unenforceable, or will not be infringed by your manufacture, use, or sale of Desloratadine and Pseudoephedrine Sulfate Extended-release Tablets, 5 mg/240 mg (24 Hour Formulation), 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 Limited (Dr. Reddy's) for infringement of one or more of these patents that were the subjects of the paragraph IV certifications. This action must have been brought against Dr. Reddy's prior to the expiration of 45 days from the date the notice you provided under section 505(j)(2)(B)(i) was received by the NDA/patent holder. You have notified the agency that Dr. Reddy's complied with the requirements of section 505(j)(2)(B) of the Act, and that litigation was initiated against Dr. Reddy's for infringement of the '274, '463, '683, and '684 patents in the United States District Court for the District of New Jersey [Schering v. Dr. Reddy's Limited, Civil Action No. 06-4715 and Sepracor Inc. and University of Massachusetts v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., Civil Action No. 07-5001]. You have notified the agency that these cases were dismissed; therefore, under section 505(j)(5)(B)(iii) your ANDA is eligible for approval.

We note that the '649 and '199 patents were not listed in the Orange Book when the Office of Generic Drugs (OGD) received your ANDA on June 21, 2006, and your paragraph IV certification was submitted in an amendment to your ANDA. Therefore, the agency has determined that, under these circumstances, a 30-month stay of approval does not apply to this 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.

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 505-1(i).

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.

You have been requested to provide information after the ANDA has been approved. Any information submitted to meet the conditions requested in this letter is considered a "Post Approval Commitment Response." To alert the Office of Generic Drug staff to the fact that you are providing post approval commitment information, please designate your submission in your cover letter as "POST APPROVAL COMMITMENT RESPONSE."

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/UCM072392.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