



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 79-043

Dr. Reddy's Laboratories, Inc.
U.S. Agent for: Dr. Reddy's Laboratories Limited
Attention: Kumara Sekar, Ph.D.
Senior Director, Regulatory Affairs
3600 Arco Corporated Drive
Suite 310
Charlotte, NC 28273-7104

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) dated June 6, 2007, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 180 mg/240 mg.

Reference is made to your amendments dated August 24, 2007; January 14, March 12 (2 submissions), June 20, August 13, and December 18, 2008; and July 21, 2009.

We have completed the review of this ANDA, and based upon the information you have presented to date we have concluded that the drug is safe and effective for use as recommended in the submitted labeling. However, we are unable to grant final approval to your ANDA at this time because of the patent issue noted below. Therefore, the ANDA is **tentatively approved**. This determination is based upon information available to the agency at this time (i.e., information in your ANDA and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention. This letter does not address issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The reference listed drug (RLD) upon which you have based your ANDA, Allegra-D 24-hour (Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 180 mg/240 mg), of Aventis Pharmaceuticals, Inc. USA, is subject to periods of patent protection. The following patents and expiration dates are currently listed in the agency's

publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

<u>U.S. Patent Number</u>	<u>Expiration Date</u>
5,578,610 (the '610 patent)	May 26, 2014
6,004,582 (the '582 patent)	May 29, 2018
6,037,353 (the '353 patent)	September 14, 2017
6,187,791 (the '791 patent)	November 11, 2012
6,399,632 (the '632 patent)	November 11, 2012
6,613,357 (the '357 patent)	December 25, 2020
7,138,524 (the '524 patent)	November 18, 2014
RE39069 (the '069 patent)	May 29, 2018

Your ANDA contains paragraph IV certifications 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 Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-Release Tablets USP, 180 mg/240 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 is brought against Dr. Reddy's Laboratories Limited (DRL) for infringement of one or more of the patents that were the subject of the paragraph IV certifications. You notified the agency that DRL complied with the requirements of section 505(j)(2)(B) of the Act, and litigation for infringement of the '353, '791, '632, '942, '912, and '872 patents was brought against DRL in the United States District Court for the District of New Jersey [Aventis Pharmaceuticals Inc., Aventis, Inc., and Carderm Capital L.P., v. Dr. Reddy's Laboratories L, Civil Action No. 07-CV-5180].

Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month period provided for in section 505(j)(5)(B)(iii),
 - b. the date the court decides¹ that the patents are invalid or not infringed (see sections 505(j)(5)(B)(iii)(I), (II), and (III) of the Act) or,
 - c. the listed patents have expired, and

¹ This decision may be either a decision of the district court or the court of appeals, whichever court is the first to decide that the patent is invalid or not infringed.

2. The agency is assured there is no new information that would affect whether final approval should be granted.

To reactivate your ANDA prior to final approval, please submit a "MINOR AMENDMENT - FINAL APPROVAL REQUESTED" 90 days prior to the date you believe that your ANDA will be eligible for final approval. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of a court decision, or a settlement or licensing agreement, as appropriate. It should also identify changes, if any, in the conditions under which the ANDA was tentatively approved, i.e., updated information such as final-printed labeling, chemistry, manufacturing, and controls data as appropriate. This amendment should be submitted even if none of these changes were made, and it should be designated clearly in your cover letter as a MINOR AMENDMENT - FINAL APPROVAL REQUESTED.

In addition to the amendment requested above, the agency may request at any time prior to the date of final approval that you submit an additional amendment containing the requested information. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your ANDA, 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 current good manufacturing practices (cGMPs) are subject to agency review before final approval of the 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 amendments prior to final approval may also result in a delay in the issuance of the final approval letter.

This drug product may not be marketed without final agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 301 of the Act. Also, until the agency issues the final approval letter, this drug product will not be deemed to be 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 application, or prior to submitting additional amendments, please contact Leigh Ann Bradford, Project Manager, at (240) 276-8453.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research