



ANDA 079043/S-003

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.  
Bridgewater, NJ 08807

Dear Sir:

This is in reference to your supplemental new drug application dated February 4, 2011, 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 (24-Hour Formulation) (OTC).

Reference is also made to your amendments dated March 21, March 29, March 31, and May 26, 2011.

This supplemental application, submitted as a "Prior Approval Supplement", provides for a change in the marketing status of the drug product from prescription (Rx) to over-the-counter (OTC) and for updated labeling to reflect the OTC status.

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 supplemental ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride Extended-release Tablets USP, 180 mg/240 mg, to be bioequivalent to the reference listed drug, Allegra-D 24 Hour Allergy and Congestion Extended-release Tablets, 180 mg/240 mg, of Sanofi Aventis US, LLC. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

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 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.

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

-----  
**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

06/22/2011

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