DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

ANDA 202978

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

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated March 30, 2011, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Fexofenadine Hydrochloride Orally Disintegrating Tablets, 30 mg (OTC).

Reference is also made to your amendments dated January 6, January 27, March 1, March 23, April 23, and June 21, 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 use as recommended in the submitted over-the counter (OTC) labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Fexofenadine Hydrochloride Orally Disintegrating Tablets, 30 mg, to be bioequivalent to the reference listed drug (RLD), Children’s Allegra Allergy Orally Disintegrating Tablets, 30 mg and Children’s Allegra Hives Orally Disintegrating Tablets, 30 mg, of Sanofi Aventis U.S., LLC (Sanofi). 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, Sanofi’s Children’s Allegra Allergy Orally disintegrating Tablets, 30 mg and Children’s Allegra Hives Orally Disintegrating Tablets, 30 mg, is subject to periods of patent protection. The following unexpired patents with 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.S. Patent Number | Expiration Date |
|---|---|
| 5,578,610 (the '610 patent) | November 26, 2013 |
| 5,738,872 (the '872 patent) | February 28, 2015 |
| 6,037,353 (the '353 patent) | March 14, 2017 |
| 7,138,524 (the '524 patent) | May 18, 2014 |

The patent information listed for the RLD (NDA 21-909) was submitted to FDA after the date of the submission of your ANDA. Sanofi, the NDA holder of record for NDA 21-909, did not timely submit these patents for listing, as required by 21 CFR 314.53(c)(2)(ii). Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of submission of these patents is required to submit an amended patent certification to address these patents.

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/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Sincerely yours,

*{See appended electronic signature page}*

Gregory P. Geba, M.D., M.P.H.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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ROBERT L WEST

01/18/2013

Deputy Director, Office of Generic Drugs, for
Gregory P. Geba, M.D., M.P.H.