



NDA 020872/S-031

**SUPPLEMENT APPROVAL**

sanofi-aventis U.S. LLC  
Attention: Mridul Shah, MS  
Assistant Director, Global Regulatory Affairs  
55 Corporate Drive, Mail Stop 55D-220B  
Bridgewater, NJ 08807

Dear Ms. Shah:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 20, 2014, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ALLEGRA® (fexofenadine hydrochloride) tablet, 180 mg.

We acknowledge receipt of your amendment dated April 10, 2014.

This “Prior Approval” sNDA proposes the addition of fexofenadine hydrochloride 180 mg gelcap tablet as a product line extension. We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

**LABELING**

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling for the 8-, 24-, and 40-count outer carton 180 mg submitted on April 10, 2014, and to the 8-count 180 mg immediate container (blister card) submitted on December 20, 2013; the FPL must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The FPL should be submitted electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 020872/S-031.**” Approval of this submission by FDA is not required before the labeling is used.

The “New! Gel Coated Tablets” flag must be removed after 180 days of marketing.

## **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

## **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Sherry Stewart, Regulatory Project Manager, at (301) 796-9618.

Sincerely,

*{See appended electronic signature page}*

Theresa Michele, M.D.  
Director  
Division of Nonprescription Clinical Evaluation  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

ENCLOSURES: Carton and Container Labeling

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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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LUCIE L YANG

04/16/2014

signing on behalf of Dr. Theresa Michele