



NDA 020872/S-029

SUPPLEMENT APPROVAL

Sanofi-Aventis, US, LLC
Attention: Nancy Dougherty
US Regulatory Affairs Marketed Products
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Dougherty:

Please refer to your Supplemental New Drug Application (sNDA) dated February 23, 2012, received February 23, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Allegra[®] Allergy (fexofenadine HCl) tablets, 60 mg and 180 mg.

We acknowledge receipt of your amendment dated March 21, 2012.

This "Prior Approval" supplemental new drug application provides for revised labeling to update the shelf presence of the Allegra[®] product line.

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

The final printed labeling (FPL) must be identical to the 12-count outer carton 60 mg, 15- and 30-count outer carton 180 mg and the 30-count 180 mg immediate container submitted on March 21, 2012. The 15-count 180 mg outer carton label and 30-count 180 mg immediate container labels serve as a representative package sizes and final printed labeling for the representative package size must be submitted. Any changes approved for the 15-count 180 mg outer carton label and 30-count 180 mg immediate container will be incorporated onto the label of the 5-count outer carton and the 45-count 180 mg immediate container, which are identical to the 15-count 180 mg outer carton label and 30-count 180 mg immediate container labels with the exception of the count size.

Even though no revisions were made to the 5-count 180 mg immediate container blister, submit the 5-count immediate container label as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement. And, even though no revisions were made to the 6-count 60 mg immediate container blister, submit the 6-count 60 mg immediate container label as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement. Submit final printed

labeling, as soon as they are available, but no more than 30 days after they are printed, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

The final printed labeling 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-029.**” Approval of this submission by FDA is not required before the labeling is used.

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.

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:

Immediate Container and Carton Labeling

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

/s/

ANDREA LEONARD SEGAL
08/23/2012