DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20872/S-25

SUPPLEMENT APPROVAL

Sanofi-Aventis, U.S., LLC
Attention: Nancy Dougherty
Specialist Base Business Product Support
55 Corporate Drive MailStop: 55C-205A
Bridgewater, NJ 08807

Dear Ms. Dougherty:

Please refer to your Supplemental New Drug Application (sNDA) dated August 23, 2011, received August 23, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Children's Allegra® Allergy and Children's Allegra® Hives (fexofenadine HCl) tablets, 30mg, and Allegra® Allergy and Allegra® Hives, (fexofenadine HCl) tablets, 60mg and 180mg .

We also refer to your amendments dated January 25, 2012.

This Prior Approval supplemental new drug application provides for new labeling for the new packaging configurations (new count sizes) referenced below and coupon labeling (stickers and coupons to be inserted inside the carton) for the Allegra® Allergy (fexofenadine HCl) tablets, 180mg drug product.

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, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed 35-count, 36-count, 37-count, 40-count, 52-count, and 54-count immediate container labels, and Sticker Coupon for the carton label (30-count) submitted on August 23, 2011, the Coupon to be inserted in the carton label(5- and 15-count), Coupon to be inserted in the carton label (30- and 45-count), and the 35-count, 36-count, 37-count, 40-count, 52-count, and 54-count carton labels submitted on January 25, 2012, 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-025.**" 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}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Labeling

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

/s/

JOEL SCHIFFENBAUER
02/23/2012