DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021704/ S-008

SUPPLEMENT APPROVAL

Sanofi-aventis, LLC
Attention: Judith R. Plon, B.S., M.B.A.
Senior Director
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Plon:

Please refer to your Supplemental New Drug Application (sNDA) dated March 25, 2010, received March 25, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra-D® 24 Hour Allergy & Congestion (fexofenadine HCl/ pseudoephedrine HCl) extended-release tablets, 180 mg/ 240 mg.

We acknowledge receipt of your submissions dated May 10 and 14, June 16 and 24, July 9 and 16, August 20 and 27, September 1, 3, and 28, October 27 and 29, December 8, 2010 and January 11, 2011.

This supplemental new drug application provides for the nonprescription use of Allegra-D® 24 Hour Allergy & Congestion for the temporary relief of symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy, watery eyes and itching of the nose and throat, the reduction of swelling of the nasal passages, the temporary relief of sinus congestion and pressure, and the temporary restoration of freer breathing through the nose in adults and children 12 years of age and older.

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 labeling (5-count immediate container (blister card) and 5- and 10-count carton labels submitted on January 11, 2011), 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 21704/S-008**." Approval of this submission by FDA is not required before the labeling is used.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

Please send to:

LCDR Jessica M. Diaz
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 5483
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

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.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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 Jessica M. Diaz, Regulatory Project Manager, at (301) 796-4908.

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):
Carton and Container 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
01/24/2011