DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20786/S-026 **SUPPLEMENT APPROVAL**

Sanofi-Aventis
55 Corporate Drive
PO Box 5925
Bridgewater, NJ 08807-0890

Attention: Gregory Urbancik
U.S. Regulatory Affairs Marketed Products

Dear Mr. Urbancik:

Please refer to your February 24, 2010, Supplemental New Drug Application (sNDA), received February 24, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Allegra-D® 12 hour (fexofenadine HCL 60mg/pseudoephedrinie HCL120mg) Extended Release Tablets.

We acknowledge receipt of your submission dated February 24, 2010.

This "Changes Being Effected" supplemental new drug application provides for the addition of ischemic colitis under the ADVERSE REACTIONS section for pseudoephedrine hydrochloride in the package insert.

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 enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] submitted on February 24, 2010.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit 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 to the labeling submitted February 24, 2010. For administrative purposes, please designate this submission "**SPL for approved NDA 20786/S-026**."

LETTERS TO HEALTH CARE PROFESSIONALS

If you 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 an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Miranda Raggio, Senior Regulatory Project Manager, at (301) 796-2109.

Sincerely,

{See appended electronic signature page}

Badrul A. Chowdhury, M.D., Ph.D.
Division of Pulmonary, Allergy, and Rheumatology Products
Office of Drug Evaluation II
Office of New Drugs
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20786	SUPPL-26	SANOFI AVENTIS US LLC	ALLEGRA D

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

/s/

BADRUL A CHOWDHURY
04/14/2010