DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-786/S-012

Aventis Pharmaceuticals
399 Interpace Parkway
Parsipanny NJ 07054

Attention: Alan Bergstrom
Senior Manager
US Drug Regulatory Affairs & Compliance

Dear Mr. Bergstrom:

Please refer to your supplemental new drug application dated March 1, 2001, received March 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra-D (fexofenadine HCl 60 mg and pseudoephedrine HCl 120 mg) Extended-Release tablets.

This supplemental new drug application provides for the addition of a paragraph to the ADVERSE REACTIONS section describing adverse events reported during controlled clinical trial in fexofenadine, involving seasonal allergic rhinitis and chronic idiopathic urticaria.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on March 1, 2001.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Christine Yu, Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Badrul Chowdhury
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