DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-872/S-015

Aventis Pharmaceuticals, Inc.
200 Crossing Blvd.
P.O. Box 6890
Bridgewater, NJ 08807-0890

Attention: Lori Birkenberger, Ph.D.
Global Regulatory Liaison

Dear Dr. Birkenberger:

Please refer to your supplemental new drug application dated December 13, 2004, received December 14, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine) tablets.

We acknowledge receipt of your submissions dated March 18, April 13 and 28, May 25, July 26, September 13 and 30, and October 5, 2005.

This supplemental new drug application provides for Allegra (fexofenadine) 180 mg tablets used once daily in chronic idiopathic urticiaria (CIU).

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert) and submitted labeling (immediate container labels submitted December 13, 2004). These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-872/S-015**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note your request for a deferral of pediatric studies for children under 6 years of age. At this time, we are waiving the pediatric study requirement for children less than 12 years of years.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Pulmonary and Allergy Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications
Food and Drug Administration
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Christine Yu, R.Ph., Regulatory Project Manager, at (301) 796-1316.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Text for approved Package Insert

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

10/13/2005 04:07:54 PM