DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-704

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

Attention: Kimberly Stranick, Ph.D.
Director, Regulatory Liaison, US Regulatory Affairs

Dear Dr. Stranick:

Please refer to your new drug application (NDA) dated and received December 19, 2003, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Allegra-D 24 Hour (fexofenadine HCl 180 mg/pseudoephedrine HCl 240 mg) Extended-Release Tablets.

We acknowledge receipt of your submissions dated February 17, March 3 and 5, April 9 and 27, May 26, June 30, July 13 and 19, August 26, September 22, 29, and 30, and October 11, 12, and 14, 2004.

This new drug application proposes the use of Allegra-D 24 Hour (fexofenadine HCl 180 mg and pseudoephedrine HCl 240 mg) Extended Release Tablets, a once a day dosage form of this combination, for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 12 years of age and older.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to enclosed labeling (text for the package insert) and submitted labeling (immediate container and carton submitted September 29, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We remind you that the changes to the (b)(4)------- equipment as discussed in your September 22 and 30, 2004, amendments to the NDA wil---------- approved as a prior approval supplement before commercial product manufactured with these changes may be marketed.

We also remind you of the Chemistry, Manufacturing, and Controls (CMC) agreements in your submission dated October 18, 2004.

One of the drugs in your combination product, pseudoephedrine HCl extended-release, is a listed drug product that is subject to a period of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), U.S. Patent No. 4801461 (the '461 patent) is scheduled to expire on March 14, 2006. Your application contains a patent certification to the '461 patent under section 505(b)(2)(A)(iv) of the Act ("paragraph IV

certification") stating that the patent is invalid and will not be infringed by your manufacture, use, or sale of Allegra-D 24 Hour ER Tablets. Section 505(c)(3)(C) of the act provides that approval of a 505(b)(2) application with a paragraph IV certification may be made effective upon expiration of 45 days from the date the notice provided under paragraph section 505(b)(3) is received by the patent holder. This means that, normally, the application cannot be approved until at least 45 days have elapsed since the notice was received by the patent holder. However, in this case, we note that you have entered into a licensing agreement with the patent holder, ALZA Corporation, as per your submission dated October 12, 2004. ALZA stated in their letter, dated October 11, 2004, that they do not intend to file an action for patent infringement against Aventis or its affiliates or sublicensees based on a claim that the sale of Allegra-D 24 Hour infringes the '461 patent. Further, in their letter, ALZA expressly consents to FDA's approval of Aventis' 505(b)(2) application for Allegra-D 24 Hour with an immediate effective date on or after the date of their letter, October 11, 2004.

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 have waived the pediatric study requirement for children less than 12 years of age for this application in our NDA acknowledgement letter dated January 14, 2004.

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 & Allergy Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
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) 827-1051.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Text of 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

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