DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-625/S-010
NDA 20-872/S-003

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

Attention: Eric Floyd, Ph.D.
Sr. Director, U.S. Regulatory Affairs

Dear Dr. Floyd:

Please refer to your supplemental new drug applications dated July 12, 2000, received July 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine HCl) capsule and tablets.

We acknowledge receipt of your submissions dated July 31, 2000, May 21, 2001, February 12 and 19, June 1, August 7, 12, and 13, December 17, 2002, and April 28, 2003.

Your December 17, 2002, submission constituted a complete response to our August 12, 2002, approvable action letter.

These supplemental new drug applications provide for changes to the package insert, to include additional safety and pharmacokinetic information in children 2 – 5 years of age. (This is not an approval of indication in this age group.)

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the editorial revision listed below and as indicated in the enclosed labeling.

> Under the PRECAUTIONS section, "Pediatric Use" subsection, the fifth paragraph should read as follows:
>
> "The safety and effectiveness of fexofenadine hydrochloride in pediatric patients under 6 years of age have not been established."

The final printed labeling (FPL) must be identical, and include the minor editorial revision indicated, to the enclosed labeling (text for the package insert). These revisions are terms of the approval of these applications.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount ten

of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-625/S-010 and NDA 20-872/S-003." Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Christine Yu, R.Ph., Regulatory Management Officer, LCDR, U.S.PHS 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

Attachment: Approved labeling text

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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