Aventis Pharmaceuticals Inc.
c/o Quintiles, Inc.
P.O. Box 9627
Kansas City, Missouri 64134-0627

Attention: Wayne F. Vallee, R.Ph.
Manager
Drug Regulatory Affairs

Dear Mr. Vallee:

Please refer to your new drug application (NDA) dated July 17, 1998, received July 17, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) 30, 60, and 180 mg Tablets.

We acknowledge receipt of your submissions dated July 30 and 31, August 13 and 25, September 29, October 28, November 10, 20 and 23, December 10 and 16, 1998, February 16, May 6, 13, 14, 21 and 24, June 4, 11, and 18, August 26, October 15, December 6 and 15, 1999, January 7, 2000. Your submission of August 27, 1999, constituted a complete response to our July 16, 1999, action letter.

This new drug application provides for the use of Allegra (fexofenadine hydrochloride) Tablets for the relief of symptoms associated with seasonal allergic rhinitis and the treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 years of age and older.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and submitted draft labeling (immediate container and carton labels submitted October 15, 1999). 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 of your commitment to revise the immediate carton and container labels to version 3 of your telephone facsimile dated February 25, 2000, at the next printing.

Please submit 20 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 NDA

20-872." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, 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 (63 *FR* 66632)(21 CFR 314.55 (or 601.27)). The Agency has not made a determination if a health benefit would be gained by studying Allegra Tablets in pediatric patients for its approved indications. FDA is deferring submission of additional pediatric assessments of safety and effectiveness that may be required under these regulations until FDA further considers the need for any additional safety or effectiveness data. FDA will inform you on or before August 25, 2000, whether additional pediatric studies are required under the rule. If FDA determines at that time that pediatric studies are necessary, FDA will also set a specific time at which you must submit the required assessments.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

Please submit one market package of the drug product for each strength when it is available.

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, contact LCDR James Lindsay Cobbs, Regulatory Project Manager, at (301) 827-1051.

Sincerely,

Robert J. Meyer, M.D.
Director
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research