CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S-001, S-002, S-004

APPROVAL LETTER

NDA 20-872/S-001

Aventis Pharmaceuticals
10236 Marion Park Drive
P.O. Box 9627
Kansas City, MO 64134-0627

Attention: Dhiren N. Shah, Ph.D.
Director, CMC, US Drug Regulatory Affairs

Dear Dr. Shah:

Please refer to your supplemental new drug application dated February 28, 2000, received February 29, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine HCl) Tablets.

We also acknowledge receipt of your submission dated March 31, 2000.

This supplemental new drug application provides for [redacted] as an additional blister packaging site.

We have completed the review of this supplemental application as amended, and it is approved.

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. Ladan Jafari, Regulatory Project Manager, at 301-827-5584.

Sincerely,

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

NDA 20-872/S-002

Aventis Pharmaceuticals Inc.
10236 Marion Park Drive
P.O. Box 9627
Kansas City, Missouri 64134-0627

Attention: J. Michael Nicholas, Ph.D.
Director US Drug Regulatory Affairs

Dear Dr. Nicholas:

Please refer to your supplemental new drug application dated March 1, 2000, received March 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Tablets.

This supplemental new drug application provides for the addition of a blister package for the 30 and 180 mg strength tablets with 18 months of expiration dating period for each.

We have completed the review of this supplemental application and it is approved.

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. Gretchen Trout, Regulatory Project Manager, at (301) 827-1058.

Sincerely yours,

Guirag Poochikian, Ph.D.
Chemistry Team Leader
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

NDA 20-872/S-004

Aventis Pharmaceuticals
10236 Marion Park Drive
P.O. Box 9627
Mail Station J5-M1540
Kansas City, MO 64134-0627

Attention: Carol Childers, Pharm.D.
U.S. Regulatory Affairs - CMC

Dear Dr. Childers:

Please refer to your supplemental new drug application dated September 14, 2000, received September 15, 2000, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) 180 mg Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an alternate manufacturing process for the 180 mg strength drug product. This alternative process includes changes in the [redacted] process parameters relative to the process approved in the original application.

We have completed the review of this supplemental application, and it is approved.

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. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely,

Guirag Poochikian, Ph.D.
Chemistry Team Leader,
Division of Pulmonary and Allergy Drug Products, HFD-570
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research