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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW #1

1. ORGANIZATION	2. NDA NUMBER
HFD-570 DPADP	20-872

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Aventis Pharmaceuticals
10236 Marion Park Drive, P.O. Box 9627
Kansas City, MO

4. AF NUMBER

5. SUPPLEMENT(S)
NUMBER(S) DATES(S)
SCP-002 3/1/00

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra® Tablets	fexofenadine hydrochloride tablets

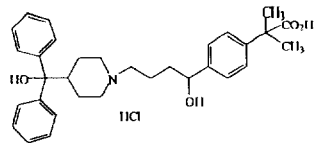
8. SUPPLEMENT PROVIDES FOR: The addition of a blister packages for the 30 mg and 180 mg strength product. The proposed expiration dating period for the 180 mg strength product packaged in blisters is 18 months, as outlined in the GC of 3/3/00. The proposed expiration dating period for the 30 mg strength is 18 months when packaged in blisters.

9. AMENDMENT(S), REPORT(S), ETC.
SCP-002 (BC) 3/2/00
GC 3/3/00

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
Histamine H_1-receptor antagonist	RX X OTC	[redacted]

13. DOSAGE FORM(S)	14. POTENCY
tablets	30, 60, and 180 mg

15. CHEMICAL NAME AND STRUCTURE
(±)-4-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-dimethylbenzeneacetic acid hydrochloride (MDL 16,455A)



16. RECORDS AND REPORTS
CURRENT YES__ NO__
REVIEWED YES__ NO__

17. COMMENTS: See attached review notes.

cc:
Orig. NDA 20-872
HFD-570/div. File
HFD-570/CBertha/3/14/00
HFD-570/GPoochikian
HFD-570/GTrout/LCobbs
R/D Init. by:_____
F/T by: CBertha/3/14/00

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be **approved**. The CMC recommendation to approve is also based on the statistical consult review from B. Elashoff of 7/12/99 and the recalculations described in the attachment 1 to the current review. Note that the applicant has made two commitments with regard to the labeling provided in the supplement and these are detailed in the telephone conference memorandum dated 3/14/00 in attachment 2 to this review.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		3/14/00

CHEMIST'S REVIEW #1

1. ORGANIZATION	2. NDA NUMBER
HFD-570 DPADP	20-872

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Aventis Pharmaceuticals
10236 Marion Park Drive, P.O. Box 9627
Kansas City, MO

4. AF NUMBER

5. SUPPLEMENT(S)
NUMBER(S) DATES(S)
SCS-004 9/14/00

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra® Tablets	fexofenadine hydrochloride tablets

8. SUPPLEMENT (CBE-30) PROVIDES FOR: The addition of an alternate manufacturing process for the 180 mg strength drug product which includes changes in [redacted] relative to the process approved in the original application.

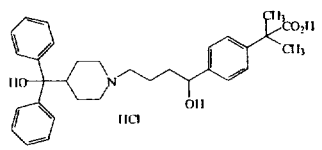
9. AMENDMENT(S), REPORT(S), ETC.

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED
Histamine H_1-receptor antagonist	RX X OTC

12. RELATED IND/NDA/DMF
[redacted]

13. DOSAGE FORM(S)	14. POTENCY
tablets	30, 60, and 180 mg

15. CHEMICAL NAME AND STRUCTURE
(±)-4-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-dimethylbenzeneacetic acid hydrochloride (MDL 16,455A)



16. RECORDS AND REPORTS
CURRENT YES__NO__
REVIEWEDYES__NO__

17. COMMENTS: See attached review notes.

cc:
Orig. NDA 20-872
HFD-570/div. File
HFD-570/CBertha/9/28/00
HFD-570/GPoochikian
HFD-570/VBorders
R/D Init. by:_____
F/T by: CBertha/9/28/00

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be **approved** for the 180 mg strength of the product only.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		9/28/00

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

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

ADMINISTRATIVE DOCUMENTS

PROJECT MANAGER LABELING REVIEW

NDA: 20-872

DATE: March 14, 2000

DRUG: Allegra Tablets

SUBMISSION DATE: March 1, 2000

SUBMISSION CODE: SCP-002

SPONSOR: Aventis Pharmaceuticals, Inc.

PROJECT MANAGER: LCDR James Lindsay Cobbs

This prior approval supplement dated March 1, 2000, received March 2, 2000, provides for blister packaging and physician sample labeling for the 30 and 180 mg tablets.

I have completed review of the carton labels provided. The carton labels are not consistent with the carton and container labels as revised and referenced in the Approval letter dated February 25, 2000. Aventis committed to revise the immediate carton and container labels to version 3 of the telephone facsimile dated February 25, 2000, at the next printing. The physician sample carton labels should be amended to be consistent with the approved immediate carton and container labels.

Aventis committed to amend the physician labels to be consistent with the immediate carton and container labels (i.e., "Tablets" should be prominently displayed as part of the established name) and the NDA holder's name should be updated to reflect the new name "Aventis Pharmaceuticals Inc." in the teleconference dated March 14, 2000.

_____ _____

LCDR James Lindsay Cobbs Date
Regulatory Project Manager

TELECON RECORD

Date: **March 14, 2000**

NDA: **20-872**

Product: **Allegra Tablets**

FDA Participant: LCDR James Lindsay Cobbs
Regulatory Project Manager

Sponsor: Dhiren Shah
Director-Regulatory CMC
US Drug Regulatory Affairs
Aventis Pharmaceuticals Inc.

Background: A brief teleconference was held to discuss the physician sample labels provided in the March 1, 2000, prior approval (PA) supplement.

1. The sponsor committed to make the physician sample labels consistent with the immediate carton and container labels as committed and referenced in the Approval letter dated February 25, 2000, at the next printing.

2. The sponsor committed to update the applicant's name to Aventis Pharmaceuticals, Inc. at the next printing.