CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-872 /S008

Trade Name: Allegra Tablets

Generic Name: fexofenadine

Sponsor: Avenits Pharmaceuticals Inc.

Approval Date: February 2, 2002

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APPLICATION NUMBER:

20-872/S008

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APPLICATION NUMBER:

20-872/S008

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-872/S-008

Aventis Pharmaceuticals, Inc.
10236 Marion Park Drive
P.O. Box 9720
Mail Stop J5-M1540
Kansas City, MO 64134-0720

Attention: Alan Martin
U.S. Drug Regulatory Affairs- CMC

Dear Mr. Martin:

Please refer to your supplemental new drug application dated January 11, 2002, received January 17, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine HCl) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for change in the film-coating for the tablets. The supplemental application was filed as per the SUPAC-IR Guidance: Immediate Release Solid Oral Dosage Forms Scale-Up and Post approval changes CMC documentation.

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 Christine Yu, R.Ph., Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

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

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/s/

Guiragos Poochikian
2/20/02 11:41:16 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S008

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)
SCM-008 1/11/02

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

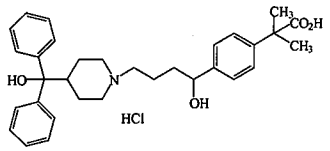
8. SUPPLEMENT (CBE-30) PROVIDES FOR: Change in the film-coating for the tablets. The supplemental application was filed as per the SUPAC-IR guidance.

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

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
Histamine H_1-receptor antagonist	RX X OTC	IND 43,573

13. DOSAGE FORM(S)	14. Potency
tablets	60 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/2/1/02
HFD-570/GPoochikian
HFD-570/CYu
R/D Init. by:_____
F/T by: CBertha/2/1/02
doc # 02-01-11.rev.doc

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be **approved (AP).**

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		2/1/02

7 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry 20572
5008

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/s/

Craig Bertha
2/4/02 06:26:39 AM
CHEMIST

Guiragos Poochikian
2/5/02 05:18:10 PM
CHEMIST