CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-872 /S010

Trade Name: Allegra Tablets

Generic Name: fexofenadine

Sponsor: Avenits Pharmaceuticals Inc.

Approval Date: October 10, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S010

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APPLICATION NUMBER:

20-872/S010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-872/S-010

Aventis Pharmaceuticals
10236 Marion Park Drive
P.O. Box 9720
Kansas City, MO 64134-0720

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

Dear Dr. Shah:

Please refer to your supplemental new drug application dated September 4, 2002, received September 5, 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 the addition of an alternate manufacturing process for the 60 mg strength tablet which includes changes [redacted] relative to process approved in the original application.

We completed our review of this supplemental new drug application, and it is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Ms. 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/

Craig Bertha
10/10/02 01:06:38 PM
for G. Poochikian

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S010

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)
SCS-010 9/4/02 (assigned 9/9/02)

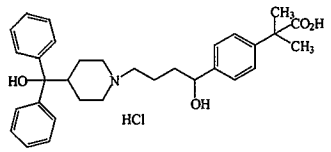
6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra® Tablets	fexofenadine hydrochloride tablets

8. SUPPLEMENT (CBE-30) PROVIDES FOR: The addition of an alternate manufacturing process for the 60 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	12. RELATED IND/NDA/DMF
Histamine H_1-receptor antagonist	RX X OTC	IND 43,573
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. Note that an analogous supplement (S-004) was approved for the 180 mg strength on 5/30/01.

cc:
Orig. NDA 20-872
HFD-570/div. File
HFD-570/CBertha/9/23/02
HFD-570/GPoochikian
HFD-570/CYu
R/D Init. by:_____
F/T by: CBertha/9/23/02
doc # 02-09-04.rev.doc

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be **approved** for the 60 mg strength of the product.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		9/23/02

4 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry 20872
S010

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/s/

Craig Bertha
9/27/02 06:33:04 AM
CHEMIST

Guiragos Poochikian
10/1/02 09:33:19 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-872/S-010

Aventis Pharmaceuticals
10236 Marion Park Drive
P.O. Box 9720
Kansas City, MO 64134-0720

CBE-30 SUPPLEMENT

Attention: Dhiren N. Shah, Ph.D.
Director, CMC- U.S. Drug Regulatory Affairs

Dear Dr. Shah:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product:	Allegra (fexofenadine HCl) tablets
NDA Number:	20-872
Supplement number:	S-010
Date of supplement:	September 4, 2002
Date of receipt:	September 5, 2002

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," provides for the use of an additional manufacturing process ——— the manufacture of Allegra 60 mg tablets. Aventis proposes to use the ——— as an alternate to the current manufacturing process.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on November 4, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be March 5, 2003.

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Drug Products, HFD-570
Attention: Fishers Document Room, 8B-45
5600 Fishers Lane
Rockville, Maryland 20857

If you have any questions, call Ms. Christine Yu, R.Ph., Regulatory Project Manager, at (301) 827-1051.

Sincerely,

{See appended electronic signature page}

Sandy Barnes
Chief, Project Management Staff
Division of Pulmonary and Allergy Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

Christine Yu
9/18/02 04:28:53 PM
Signing for Sandy Barnes, CPMS