CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-872 /S005

Trade Name: Allegra Tablets

Generic Name: fexofenadine

Sponsor: Avenits Pharmaceuticals Inc.

Approval Date: January 5, 2001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S005

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

20-872/S005

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-872/S-005

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

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

Dear Dr. Shah:

Please refer to your supplemental new drug application dated October 11, 2000, received October 12, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Tablets.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of an alternate blister packaging site for the drug product.

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 Vicky Borders, Pharm.D., Regulatory Project Manager, at (301) 827-5585.

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

/s/

Alan Schroeder
1/5/01 03:37:54 PM
Signed for Dr. Guirag Poochikian.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S005

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-005 10/11/00

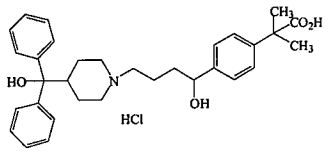
6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra® Tablets	fexofenadine hydrochloride tablets

8. SUPPLEMENT (CBE-30) PROVIDES FOR: The supplement provides for the addition of an alternate blister packaging site for the drug product.

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.

cc:
Orig. NDA 20-872
HFD-570/div. File
HFD-570/CBertha/10/30/00
HFD-570/GPoochikian
HFD-570/VBorders
R/D Init. by:_____
F/T by: CBertha/10/30/00
doc # 00-10-11.rev.doc

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be approved pending the confirmation of the packaging site as acceptable (AC) by the Office of Compliance. The PM should note that the EES request was submitted on 10/30/00 and a response is pending.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		10/30/00

1 Page(s) Withheld

1 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-870
S005

/s/

Craig Bertha
11/2/00 11:54:24 AM
CHEMIST

Guiragos Poochikian
11/2/00 02:55:05 PM
CHEMIST