CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-872 /S009

Trade Name: Allegra Tablets

Generic Name: fexofenadine

Sponsor: Avenits Pharmaceuticals Inc.

Approval Date: December 10, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S009

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S009

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-872/S-009

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

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

Dear Dr. Shah:

Please refer to your supplemental new drug application dated June 11, 2002, received June 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine) tablets.

We acknowledge receipt of your submissions dated July 3 and 17, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of the Aventis Pharma Laval, Quebec, Canada site as an alternate site for the manufacture, packaging, labeling, and testing of the 180 mg strength of the drug product (does not apply to the other approved strengths, 30 and 60 mg).

We have completed our review of this supplemental new drug application, as amended, 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/

Guiragos Poochikian
12/10/02 05:02:10 PM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S009

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-009 6/11/02 (assigned 6/14/02)

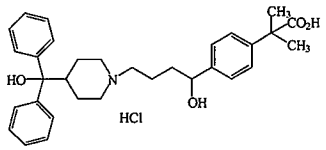
6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra® Tablets	fexofenadine hydrochloride tablets

8. SUPPLEMENT (CBE-30) PROVIDES FOR: the addition of the Aventis Pharma Laval, Quebec, Canada site as an alternate site for the manufacture, packaging, labeling, and testing of the 180 mg strength of the drug product (does not apply to the other approved strengths, 30 and 60 mg). The supplemental application was filed as a CBE-30 as per the Changes to Approved NDAs/ANDAs 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	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/7/10/02
HFD-570/GPoochikian
HFD-570/CYu
R/D Init. by:_____
F/T by: CBertha/7/10/02
doc # 02-06-11.rev.doc

18. CONCLUSIONS AND RECOMMENDATIONS: Based on the CMC information provided, it is recommended that the supplement be **approved (AP)** pending an ACCEPTABLE recommendation from OC for the Laval, Canada DP manufacturing site (inspection request submitted on 6/24/02 and inspection assigned on 7/1/02).

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		7/10/02

5 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-872 / S009

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/s/

Craig Bertha
7/10/02 06:13:15 AM
CHEMIST

Guiragos Poochikian
7/10/02 12:45:47 PM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-872/S009

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-872/S-009

CBE-30 SUPPLEMENT

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

Attention: Dhiren N. Shah, Ph.D.
Director, 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) 180 mg tablet

NDA Number: 20-872

Supplement Number: S-009

Date of Supplement: June 11, 2002

Date of Receipt: June 12, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected in 30 days" supplement, proposes an additional manufacturing, packaging, labeling, testing and release site for the Allegra 180 mg tablets.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 11, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be December 12, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary and Allergy Drug Products, HFD-570
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

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

Sincerely,

{See appended electronic signature page}

Sandy Barnes
Supervisory CSO
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
6/17/02 11:42:09 AM
Signing for Sandy Barnes, CPMS

Record of Telephone Conversation

Date: July 16, 2002
NDA No: NDA 20-872
Product Name: Allegra Tablets
(fexofenadine hydrochloride)

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

Telecon Initiated by: Firm

Name and Title of Persons with whom conversation was held:
Sanjay K. Nimkar, Ph.D.

Telephone No: (816)-966-4352

Background: The Agency inquired about the Aventis Laval, Canada drug product manufacturing site being proposed for use for preparation of the 180 mg strength of the product and a correspondence to the application was forwarded dated 7/3/02 that indicated that the site had been inspected by the FDA on Aug. 17-21, 2001.

Content of Telecon: Dr. Nimkar stated that the earlier correspondence of 7/3/02 was in error and that the FDA inspection had taken place Aug. 17-21, 1998. I asked Dr. Nimkar to submit this correction in writing and that ended the conversation. The 7/17/02 correspondence provides the corrected inspection date.

Post Telecon Note: An EES was forwarded to OC on June 24, 2002 and an inspection of the facility was scheduled on July 1, 2002. Presumably the OC had knowledge that the last inspection of the facility was more than 2 years prior when assigning the current inspection of the Laval site.

Craig M. Bertha, Ph.D.
HFD-570

cc:
Orig. NDA 20-872
HFD-570/Division File
HFD-570/CBertha/7/19/02
HFD-570/GPoochikian
HFD-570/CYu
R/D Init. by:
F/T by: CBertha 7/19/02
doc. name 02-07-16.tel.doc

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/s/

Craig Bertha
7/19/02 01:05:11 PM
CHEMIST