CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-786 /S001
20-625/S006

Trade Name: Allegra Tablets
Allegra Extended Release Tablets

Generic Name: fexofenadine hydrochloride
fexofenadine hydrochloride/pseudoephedrine

Sponsor: Hoechst Marion Roussel

Approval Date: July 6, 1998

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-786 /S001

20-625/S006

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-786 /S001

20-626/S006

APPROVAL LETTER

NDA 20-625/S-006
NDA 20-786/S-001

JUL – 6 1998

Hoechst Marion Roussel
10236 Marion Park Drive
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 applications dated June 5, 1998, received June 8, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Tablets and Allegra-D (fexofenadine hydrochloride/pseudoephedrine) Extended-Release Tablets.

The user fee goal date for these applications is December 8, 1998.

We note that these supplements were submitted as 'Special Supplement - Changes Being Effected' under 21 CFR 314.70(c).

These supplemental new drug applications provide for the addition of an alternate packaging site for the drug products.

We have completed the review of these supplemental applications and they are 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, contact Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely,

Guirag Poochikian, Ph.D.
Chemistry Team Leader, DNDC II for the
Division of Pulmonary Drug Products, (HFD-570)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Archival NDAs 20-625, 20-786
HFD-570/Div. Files
HFD-570/G.Trout GST 7/2/98
HFD-570/Bertha CB 7/6/98
HFD-570/Poochikian for GP 7/6/98
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: GST/July 1, 1998

Initialed by: Schumaker/7-1-98
Bertha/7-2-98
Rogers (for Poochikian)/7-2-98

final: Trout/7-2-98

filename: n:\staff\troutg\20625.let

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-786 /S001

20-625/S006

CHEMISTRY REVIEW(S)

JUN 22 1998

CHEMIST'S REVIEW #1

1. ORGANIZATION	2. NDA NUMBER
HFD-570 DPDP	20-625

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Hoechst Marion Roussel, Inc.
Kansas City, MO

4. AF NUMBER

5. SUPPLEMENT(S)
NUMBER(S) DATES(S)
SCP-006 6/5/98

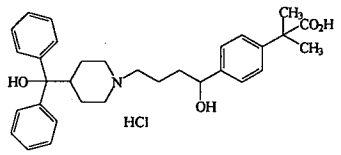
6. NAME OF DRUG	7. NONPROPRIETARY NAME
Allegra Capsules	fexofenadine hydrochloride capsules

8. SUPPLEMENT PROVIDES FOR: The supplement provides for the addition of an alternate packaging site for the drug product. Although this is an immediate release solid oral dosage form, the applicant has filed the supplement as per section V. of the SUPAC-MR (modified release) document.

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	
capsules	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 20-625
HFD-570/div. File
HFD-570/CBertha/6/22/98
HFD-570/GPoochikian
HFD-570/GTreut
R/D Init. by: GT 6/22/98
F/T by: CBertha/6/22/98
doc # 98-06-05.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 EES request was submitted on 6/22/98.

19. REVIEWER NAME:	SIGNATURE	DATE COMPLETED
Craig M. Bertha, Ph.D.		6/22/98

1 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-20 786
S001

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-786/S001

20-625/S006

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-625/S-006

JUN 24 1998

HOECHST MARION ROUSSEL, INC.
PO BOX 0627
10236 MARION DRIVE
KANSAS CITY, MO 64134-0627

Attention: DHIREN N. SHAH, PH.D.
DIRECTOR
CMC, US REGULATORY AFFAIRS

Dear DR SHAH:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: ALLEGRA CAPSULES

NDA Number: 20-625

Supplement Number: S-006

Date of Supplement: JUNE 5, 1998

Date of Receipt: JUNE 8, 1998

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on AUGUST 7, 1998 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Pulmonary Drug Products, HFD-570
Office of Drug Evaluation II
Attention: Document Control Room 10B-03
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

for Cathie Schumaker
Chief, Project Management Staff
Division of Pulmonary Drug Products, HFD-570
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-625/006
HFD-570/Div. Files
HFD-570/CSO/GRETCHEN TROUT

filename:

SUPPLEMENT ACKNOWLEDGEMENT

ORIGINAL

Hoechst Marion Roussel

NDA NO. 20625 REF NO. SCM-[illegible]
NDA SUPPL FOR S-5

June 5, 1998

Hoechst Marion Roussel, Inc.

10236 Marion Park Drive
Mail: P.O. Box 9627
Kansas City, MO 64134-0627
Telephone (816) 966-5000
U.S. Web site: www.hmri.com

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Pulmonary Drug Products
(HFD-570)
5600 Fishers Lane
Rockville, MD 20857

Attention: Ms. G. Trout, Regulatory Health Project Manager

Re: NDA 20-625
ALLEGRA® Capsules
(fexofenadine hydrochloride)

Special Supplement:
Changes Being Effected
Chemistry, Manufacturing, and Controls
Additional Packaging Site

Dear Ms. Trout:

In accordance with SUPAC-MR Guidance, section V, Hoechst Marion Roussel, Inc. (HMRI) hereby submits, in duplicate, a Changes Being Effected (CBE) Supplement to the above-referenced New Drug Application.

The purpose of this supplement is to provide for a stand-alone packaging operation site change for ALLEGRA® Capsules. HMRI plans to add its manufacturing site in Cincinnati, Ohio as a packaging site for ALLEGRA® Capsules utilizing containers/closures and packaging process in the approved application. The address for the site is as follows:

Merrell Pharmaceuticals, Inc. (Drug Establishment Number – 1510437)
Subsidiary of Hoechst Marion Roussel, Inc.
2110 East Galbraith Road
Cincinnati, OH 45215

The undersigned certifies that the Cincinnati facility is in compliance with cGMPs. The HMRI, Cincinnati site has a current and satisfactory cGMP compliance profile with the FDA for the type of packaging operation proposed. The facility was last inspected by the FDA during November 7, 1995 and December 5, 1995 and no 483 observations were issued at the conclusion of the inspection and there are no outstanding issues in regards to the compliance to the cGMP.

HMRI commits to place the [redacted] and annual batches thereafter of ALLEGRA® Capsules packaged at our Cincinnati site on long-term stability studies using the NDA-approved protocol and submit the resulting data in subsequent Annual Reports.

Pursuant to 21 CFR 314.71(b), we provide a true copy of this supplement to the Cincinnati FDA District Office.

Should you have any comments or questions, please contact the undersigned at (816) 966-7104.

Sincerely,
Hoechst Marion Roussel, Inc.
Mail Station H3-M2112

Dhiren N. Shah

Dhiren N. Shah, Ph.D.
Director - CMC, US Drug Regulatory Affairs

ejs

cc: Cincinnati District Office, 1411 Central Parkway, Cincinnati, OH 45202-1097

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. *0910-0297*
Expiration Date: *November 30, 1996.*

USER FEE COVER SHEET

See Instructions on Reverse Before Completing This Form.

1. APPLICANT'S NAME AND ADDRESS

Hoechst Marion Roussel, Inc.
PO Box 9627, F3-M3032
Kansas City, MO 64134-0627

2. USER FEE BILLING NAME, ADDRESS, AND CONTACT

Elaine Waller, PharmD, F3-M3032
VP, NA Drug Regulatory Affairs
Hoechst Marion Roussel, Inc.
PO Box 9627
Kansas City, MO 64134-0627

3. TELEPHONE NUMBER *(Include Area Code)*
(816) 966-5215

4. PRODUCT NAME Allegra Capsules

5. DOES THIS APPLICATION CONTAIN CLINICAL DATA? ☐ YES ☒ NO

IF YOUR RESPONSE IS "NO" AND THIS IS FOR A SUPPLEMENT, STOP HERE AND SIGN THIS FORM.

6. USER FEE I.D. NUMBER

7. LICENSE NUMBER/NDA NUMBER

8. IS THIS APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCLUSIONS? IF SO, CHECK THE APPLICABLE EXCLUSION.

☐ A LARGE VOLUME PARENTERAL DRUG PRODUCT APPROVED BEFORE 9/1/92

☐ AN INSULIN PRODUCT SUBMITTED UNDER 506

☐ THE APPLICATION IS SUBMITTED UNDER 505(b)(2) *(See reverse before checking box.)*

FOR BIOLOGICAL PRODUCTS ONLY

☐ WHOLE BLOOD OR BLOOD COMPONENT FOR TRANSFUSION

☐ BOVINE BLOOD PRODUCT FOR TOPICAL APPLICATION LICENSED BEFORE 9/1/92

☐ A CRUDE ALLERGENIC EXTRACT PRODUCT

☐ AN "IN VITRO" DIAGNOSTIC BIOLOGIC PRODUCT LICENSED UNDER 351 OF THE PHS ACT

9. a. HAS THIS APPLICATION QUALIFIED FOR A SMALL BUSINESS EXCEPTION? ☐ YES *(See reverse if answered YES)* ☐ NO

b. HAS A WAIVER OF APPLICATION FEE BEEN GRANTED FOR THIS APPLICATION? ☐ YES *(See reverse if answered YES)* ☐ NO

This completed form must be signed and accompany each new drug or biologic product, original or supplement.

SIGNATURE OF AUTHORIZED COMPANY REPRESENTATIVE	TITLE	DATE
Elaine Waller	Vice President, North American Drug Regulatory Affairs	6/5/98