CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-625 /S009
20-786/S006

Trade Name: Allegra Capsules
Allegra-D Extended Release Tablets

Generic Name: fexofenadine hydrochloride
fexofendadine hydrochloride and pseudoephedrine hydrochloride

Sponsor: Hoechst Marion Roussel, Inc.

Approval Date: January 6, 2000

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APPLICATION NUMBER:

20-625 /S009

20-786/S006

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APPLICATION NUMBER:

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APPROVAL LETTER

NDA 20-625/S-009
NDA 20-786/S-006

Hoechst Marion Roussel, Inc.
10236 Marion Park Drive
P.O. Box 9627
Kansas City, MO 64134-0627

Attention: J. Michael Nicholas, Ph.D.
Director, US Drug Regulatory Affairs

Dear Dr. Nicholas:

Please refer to your supplemental new drug applications dated October 18, 1999, received October 19, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Allegra (fexofenadine hydrochloride) Capsules and Allegra-D (fexofenadine hydrochloride and pseudoephedrine hydrochloride) Extended-release Tablets.

We acknowledge receipt of your submissions dated November 12 and December 7, 1999.

These "Changes Being Effected" supplemental new drug applications provide for an additional fexofenadine hydrochloride manufacturing site at Frankfurt, Germany.

We have completed the review of these supplemental applications, as amended, and they are approved effective on the date of this letter.

We remind you of the following agreements.

1. You will place the first three batches of fexofenadine hydrochloride produced at the HMR Frankfurt site, for production of drug products for US commerce, on long-term stability at [redacted] RH through the re-test period of [redacted] months and report data to the Agency. If a batch fails to meet the FDA-approved specifications, the resultant drug product batches from that batch of fexofenadine hydrochloride will be immediately withdrawn from the market and reported to the Agency.

2. You will place the [redacted] batch of Allegra Capsules, Allegra-D Tablets, Allegra Tablets, and Allegra Pediatric Suspension made from the fexofenadine hydrochloride manufactured at the HMR Frankfurt site on stability for [redacted] months at [redacted] RH, and on long-term stability [redacted] RH), and report the data to the Agency. If a batch fails to meet the NDA-approved specifications, that batch of the drug product will be immediately withdrawn from the market and reported to the Agency.

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 Mrs. Gretchen Trout, Project Manager, at (301) 827-1058.

Sincerely yours,

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

cc:
Archival NDAs 20-625, 20-786
HFD-570/Div. Files
HFD-570/G.Trout
HFD-570/Rogers
HFD-570/Poochikian
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: GST/January 4, 2000
Initialed by: Jani/1-6-00
Rogers/1-6-00
Poochikian/1-6-00
final: KCampbell/1-6-00
filename: n:\staff\troutg\20625ap

APPROVAL (AP)

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APPLICATION NUMBER:

20-625 /S009

20-786/S006

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

	1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-625
3. NAME AND ADDRESS OF APPLICANT (City and State) Hoechst Marion Roussel, Inc. PO Box 9627 Kansas City, MO 64134-0627	4. AF NUMBER	5. SUPPLEMENT(S) NUMBER DATE SCM-009 10/18/99
6. NAME OF DRUG Allegra 60 mg Capsules	7. NONPROPRIETARY NAME fexofenadine hydrochloride 60 mg capsules	
8. SUPPLEMENT PROVIDES FOR: An additional fexofenadine HCl manufacturing site at Frankfurt, Germany		9. AMENDMENT(S), REPORT(S), ETC. SCM-009 BC 11/12/99
10. PHARMACOLOGICAL CATEGORY Histamine H_1-receptor antagonist for treatment of seasonal allergic rhinitis	11. HOW DISPENSED RX X OTC __	12. RELATED IND/NDA/DMF
13. DOSAGE FORM(S) Immediate-release capsule	14. POTENCY 60 mg immediate-release fexofenadine HCl	
15. CHEMICAL NAME AND STRUCTURE (±)-4-[1-Hydroxy-4-[4-(hydroxydiphenylmethyl)-1-piperidinyl]-butyl]-dimethylbenzeneacetic acid HCl (for structure see USAN)		16. RECORDS AND REPORTS CURRENT YES_ NO_ REVIEWED YES_ NO_

17. COMMENTS: See attached

cc:
Orig. NDA #20-625
HFD-570/div. File
HFD-570/BRogers/12/22/99
HFD-570/GPoochikian
HFD-570/GTrout
R/D Init. by:_____
F/T by: B. Rogers/12/22/99
doc # 20625.s09.DOC

18. CONCLUSIONS AND RECOMMENDATIONS: The supplement is APPROVED. The PM should include the commitments in the "Comments to the Applicant" section of this review in the Approval letter.

19. REVIEWER NAME	20. SIGNATURE	21. DATE COMPLETED
Brian D. Rogers, Ph.D.		12/22/99

13 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry-20625
5009