CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998/S-009

CONTENTS

Reviews / Information Included in this NDA Review.	
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Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
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EA/FONSI	
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Correspondence	
Bioresearch Monitoring	

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 18-998/S-009

Trade Name: Vasotec

Generic Name(s): (enalaprilat)

Sponsor: Merck Sharp & Dohme Research Laboratories

Agent:

Approval Date: July 10, 1987

Indication: The treatment of hypertension.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-009

Approval Letter(s)

29.1

NDA 18-998/S-009
18-201/S-022

JUL 10 1987

Merck Sharp & Dohme Research Laboratories
Attention: Elliott T. Berger, Ph.D.
Division of Merck & Co., Inc.
West Point, PA 19486

Please refer to your March 25, 1987 supplemental new drug applications submitted under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act for Vasotec (enalapril maleate, MSD) - NDA 18-998, and Moduretic (amiloride HCl - hydrochlorothiazide, MSD) - NDA 18-201.

These supplemental applications provide for alternate packaging of your respective drug products at:

_____

_____

We have completed our review of these supplemental applications and they are approved. Our letters of December 24, 1985 (NDA 18-998) and October 5, 1981 (NDA 18-201) detailed the conditions relating to the approval of these applications.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

RJW 7/9/87

Robert J. Wolters
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Research and Review
Center for Drugs and Biologics

cc:
Orig. NDA 18-998
HFN/110
HFN/110/CSO
HFN/110/RWolters
keg/7/6/87/0739e

S. Zimmerman 7/9/87

APPROVAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-009

Chemistry Review(s)

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
HFN-110	see below

3. NAME AND ADDRESS OF APPLICANT *(City and State)*

Merck Sharp & Dohme Research Labs
West Point, PA 19486

JUL 10

4. AF NUMBER

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
see below	see below

6. NAME OF DRUG	7. NONPROPRIETARY NAME
see below	

8. SUPPLEMENT(S) PROVIDES FOR: alternate packaging

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
individualized	☒ RX ☐ OTC	Packaging DMF *

13. DOSAGE FORM (S)	14. POTENCY *(Ies)*
individualized	individualized

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS

CURRENT ☐ YES ☐ NO

REVIEWED ☐ YES ☐ NO

17. COMMENTS

	NDA Numbers	S#	Trade Name	Submission Date
1.	18-201	022	Moduretic	3/25/87
2.	18-998	009	Vasotec	3/25/87

An inspection (GMP) request was made on 6/15/87. Results (6/16/87) indicate an approval action.

* Letter of authorization is dated 11/14/85.

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend an approval action. A draft letter is prepared with this review handling both subject NDAs.

NDA 18-998

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Stuart Zimmerman	Stuart Zimmerman	7/6/87

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