CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

18-998/S023

Trade Name: Vastoec

Generic Name: Enalapril maleate

Sponsor: Merck Sharp & Dohme Research Laboratories

Approval Date: July 19, 1990

Indications: The treatment of hypertension.

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APPLICATION NUMBER:

18-998/S023

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Medical Review(s)	
Chemistry Review(s)	X
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	

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APPLICATION NUMBER:

18-998/S023

APPROVAL LETTER

JUL 19 1990

NDA 18-998/S-023

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

Dear Dr. Berger:

Please refer to your April 10, 1990 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug and Cosmetic Act for Vasotec (enalapril maleate) Tablets.

This supplemental application provides for an alternate manufacturing process for packaging of Tablets ——————————————————————in

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.

Sincerely yours,

RW 7-19-90

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Orig.
HFD-110
HFD-110/CSO
HFD-110/SZimmerman/7/13/90
sh/7/13/90;7/16/90;7/17/90:5639h
R/D init: 7/16/90

APPROVAL

Approval Date: 12/24/85

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998/S023

CHEMISTRY REVIEW(S)

JUL 19 1990

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	18-998

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
MSD
West Point, Penn. 19486

4. AF NUMBER

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-023	4/10/90

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Vasotec	Enalapril Maleate

8. SUPPLEMENT(S) PROVIDES FOR:
an alternate packaging of the tablets by _____ in _____

9. AMENDMENTS AND OTHER *(Reports, etc.)* DATES
S-023 4/10/90

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
No change	☒ RX ☐ OTC	

13. DOSAGE FORM (S)	14. POTENCY *(Iea)*
No change	No change

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

17. COMMENTS
Acceptable material will be released by MSD personnel. An Inspection (GMP) Check was made (5/3/90) and an acceptable response was issued (5/14/90) and received on 7/13/90.

STS = 52

18. CONCLUSIONS AND RECOMMENDATIONS
AP action

7/16/90

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Stuart Zimmerman		7/13/90

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FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED. 1

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

1. ORGANIZATION: HFN-110

2. NDA NUMBER: 18-998

3. NAME AND ADDRESS OF APPLICANT (City and State)
MSD
West Point, Penn. 19486

4. AF NUMBER:

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-023	4/10/90

6. NAME OF DRUG: Vasotec

7. NONPROPRIETARY NAME: Enalapril Maleate

8. SUPPLEMENT(S) PROVIDES FOR:
an alternate packaging of the tablets by _____ in _____

9. AMENDMENTS AND OTHER (Reports, etc.) DATES
S-023 4/10/90

10. PHARMACOLOGICAL CATEGORY: No change

11. HOW DISPENSED: ☒ RX ☐ OTC

12. RELATED IND/NDA/DMF(S):

13. DOSAGE FORM (S): No change

14. POTENCY (Iss): No change

15. CHEMICAL NAME AND STRUCTURE

16. RECORDS AND REPORTS
CURRENT: ☐ YES ☐ NO
REVIEWED: ☐ YES ☐ NO

17. COMMENTS

Acceptable material will be released by MSD personnel. An Inspection (GMP) Check was made (5/3/90) and an acceptable response was issued (5/14/90) and received on 7/13/90.

This is a second copy that has available a second page of the Chemist's Review.

STS = 52

18. CONCLUSIONS AND RECOMMENDATIONS

AP action

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Stuart Z Immerman		7/13/90

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FORM FDH 2266 (7/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

DMF ————————

The DMF describes a plant constructed in 1985 for the manufacture/packaging of finished drug products. It was constructed under the supervision of ——— ——————————— following the principle of CGMP's. Volume 1.1 deals with this in the August 1985 submission. Assurances are offered to provide a tight and constant control. Production equipment is summarized with respect to site. Protocols appear to be acceptable for receiving and the quarantine of incoming goods.

The name and address is:

————————————
————————
————————————
————————————
————————————————

Bioavailability Status: Satisfactory.

The proposed change deals only with the use of an alternate packager and so this would not be expected to impawct on any bioavailability concerns that could be considered.

Stuart Zimmerman, Ph.D.

cc:Orig.
HFD-110
HFD-110/CSO
HFD-110/SZimmerman
sh/7/19/90:5652h