CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998/S-50

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Reviews / Information Included in this NDA Review.	
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER(S)

NDA 18-998/S-050

Trade Name: Vasotec

Generic Name(s): (enalaprilat)

Sponsor: Merck & Co., Inc.

Agent:

Approval Date: March 22, 1996

Indication: The treatment of hypertension.

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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-050

Approval Letter(s)

91-1

NDA 18-998/S-050

MAR 22 1996

Merck & Co., Inc.
Merck Research Laboratories
Attention: Larry P. Bell, M.D
P.O. Box 4, BLA-30
West Point, PA 19486-0004

Dear Dr. Bell:

Please refer to your February 13, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vasotec (enalapril maleate) 2.5, 5, 10 and 20 mg Tablets.

The supplemental application provides for a SUPAC change in the operating speed of the ———— used in the ———————— in the manufacture of the 10 mg Vastotec tablet at Merck facilities in Caguas, Puerto Rico.

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,

RJW 3/22/96

Robert J. Wolters, Ph.D.
Chemistry Team Leader, DNDC-1
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

cc:
Original NDA
Home District
HFD-110
HFD-110/Project Manager
HFD-80
HFD-232
HFD-358/JCook
HFD-110/SZimmerman/3/15/96
kc/3/14/96

Stuart Zimmerman 3/22/96

Approval Date: December 24, 1985

APPROVAL

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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-050

Chemistry Review(s)

MAR 22 1996

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 18-998
3. Name and Address of Applicant (City & State) Merck & Co., Inc. West Point, PA.		4. Supplement(s) Number(s) Date(s) S-050 2/13/96
5. Drug Name VASOTEC	6. Nonproprietary Name Enalapril Maleate	8. Amendments & Other (reports, etc) - Dates None
7. Supplement Provides For: a change in the operating speed of the _____ used in the _____ in the manufacture of Tablets VASOTEC 10 mg at Merck facilities in Caguas, Puerto Rico.		
9. Pharmacological Category NC	10. How Dispensed / / Rx / / OTC	11. Related IND(s)/ NDA(s)/DMF(s) None
12. Dosage Form(s) 10 mg size involved	13. Potency(ies) NC	
14. Chemical Name and Structure NC		15. Records/Reports Current / / Yes / / No Reviewed / / Yes / / No

16. Comments:

Generally this supplement appears to be adequate for its intended purpose since it provides qualifying information under the Support Guidance.

17. Conclusions and Recommendations: Recommend approval.

18. REVIEWER		
Name Stuart Zimmerman	Signature Stuart Zimmerman	Date Completed 3/15/96

Distribution: M Original Jacket / / Reviewer / / Division File / / CSO / / District (Home)

JWolo 3/18/96

1 Page(s) Withheld

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

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling