

# CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998 / S-042

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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-042**

**Trade Name:** Vasotec

**Generic Name(s):** (enalaprilat)

**Sponsor:** Merck & Co. Inc.  
**Agent:**

**Approval Date:** July 15, 1994

**Indication:** The treatment of hypertension.

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 18-998/S-042**

**Approval Letter(s)**

JUL 15 1994

Merck & Co., Inc.  
Attention: Patricia L. Kraft, Ph.D.  
BLA-30  
West Point, PA 19486

Dear Dr. Kraft:

Please refer to your December 23, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for VASOTEC (enalapril maleate) Tablets.

The supplemental application provides an alternate rework procedure in the manufacture of the bulk drug substance \_\_\_\_\_

As discussed by telephone on July 13, 1994, between your representative Dr. Larry Bell and Dr. Stuart Zimmerman of this agency, we understand that you will identify the composition of the \_\_\_\_\_ involved in your next annual report.

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 7-15-94*

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:

Original NDA

HFC-130/JAllen  
HFD-110  
HFD-110/CSO  
HFD-80/DDIR  
HFD-100  
HFD-110/SZimmerman/7/13/94  
clb/7/13/94;7/14/94/N18998.S42  
R/D init: RWolters/7/13/94

*Stuart Zimmerman 7/14/94*

Approval Date: December 24, 1985

APPROVAL

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 18-998/S-042**

**Chemistry Review(s)**

CHEMIST'S REVIEW	1. ORGANIZATION (DCRDP) HFD-110 (RM 16B-18)	2. NDA Number 18-998
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3. Name and Address of Applicant (City & State) Merck & Co, Inc. West Point, PA 19486	4. Supplement(s) Number(s) Date(s) S-042 12/23/93
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5. Drug Name Vasotec	6. Nonproprietary Name Enalapril Maleate	8. Amendments & Other (reports, etc) - Dates
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7. Supplement Provides For: alternate rework procedure in the manufacture of the bulk drug substance	
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9. Pharmacological Category No change	10. How Dispensed //Rx //OTC	11. Related IND(s)/ NDA(s)/DMF(s)
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12. Dosage Form(s) No change	13. Potency(ies) No change	
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14. Chemical Name and Structure No change	15. Records/Reports Current //Yes //No Reviewed //Yes //No
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16. Comments: As discussed with Merck representatives the \_\_\_\_\_ of the bulk drug substance, I talked to Dr. Bell on 7/13/94 about the need to provide the particular identity/composition of the \_\_\_\_\_ involved and he said Merck would put this in an annual report.

17. Conclusions and Recommendations:  
Recommend approval

18. REVIEWER

Name Stuart Zimmerman	Signature Stuart Zimmerman	Date Completed 7/13/94
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Distribution: // Original Jacket // Reviewer // Division File // CSO // Field