

# CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998 / 5041

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**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER(S)**

**NDA 18-998/S-41**

**Trade Name:** Vasotec

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

**Sponsor:** Merck Research Laboratories

**Agent:**

**Approval Date:** December 12, 1994

**Indication:** The treatment of hypertension.

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 18-998/S-041**

**Approval Letter(s)**

NDA 18-998/S-041

DEC 12 1994

Merck Research Laboratories  
Attention: Dr. Larry Bell  
West Point, PA 19486

Dear Dr. Bell:

Please refer to your September 15, 1993 supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vasotec (enalapril maleate) Tablets.

We acknowledge receipt of your amendments dated August 22, 1994.

The supplemental application provides for the manufacture of the bulk drug substance, enalapril maleate, at the Merck & Co., Inc. facility at La Vallee, France.

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 12-12-94*

Robert 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

HFD-232

HFD-110/SZimmerman/12/8/94

clb/12/8/94;12/9/94/N18998.S41

R/D init: RWolters/12/8/94

*Stuart Zimmerman 12/9/94*

Approval Date: December 24, 1985

APPROVAL

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 18-998/S-041**

**Chemistry Review(s)**

<b>CHEMIST'S REVIEW</b>		<b>1. ORGANIZATION (DCRDP)</b> HFD-110	<b>2. NDA Number</b> 18-998
<b>3. Name and Address of Applicant (City &amp; State)</b> Merck Research Laboratories West Point, PA 19486		<b>4. Supplement(s)</b> <b>Number(s)</b> <b>Date(s)</b> S-041                      9/15/93	
<b>5. Drug Name</b> Vasotec	<b>6. Nonproprietary Name</b> enalapril maleate		<b>8. Amendments &amp; Other (reports, etc) - Dates</b> S/A                      8/22/94
<b>7. Supplement Provides For:</b> The manufacture of the bulk drug substance at Merck & Co., Inc., La Vallee, France.			
<b>9. Pharmacological Category</b> Antihypertensive	<b>10. How Dispensed</b> /X/ Rx   // OTC		<b>11. Related IND(s)/ NDA(s)/DMF(s)</b>  _____
<b>12. Dosage Form(s)</b> No change	<b>13. Potency(ies)</b> No change		
<b>14. Chemical Name and Structure</b> No change			<b>15. Records/Reports</b> Current // Yes   // No Reviewed // Yes   // No
<b>16. Comments:</b>  This submission deals with information relating to the La Vallee facility as an aid to the foreign FDA investigators. General information falls under the evaluation of CGMPR and is not of assessment concern for this review. Specific information which relates to the subject drug only confirms that there are no control problems in terms of change control.			
<b>17. Conclusions and Recommendations:</b>  Recommend approval and send the firm an approval letter.			
<b>18. REVIEWER</b>			
<b>Name</b> Stuart Zimmerman	<b>Signature</b> <i>Stuart Zimmerman</i>		<b>Date Completed</b> 12-8-94
<b>Distribution:</b> // Original Jacket   // Reviewer   // Division File   // CSO   // District			

*Wald 12-9-94*

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**NDA 18-998/S-041**

**Administrative/Correspondence**

**LISTING OF RECENT FDA/FIRM INTERACTIONS**

<u>Date*</u> :	<u>Comments</u>
7-12-94	FAX from S. Zimmerman (FDA, HFD-110) to Larry Bell (Merck) concerning documental support for proposed change.
7-7-94	FAX from S. Zimmerman (FDA, HFD-110) to Larry Bell (Merck) concerning the inspectional status of this supplement.

\*Inverse chronology

**INSPECTIONAL STATUS**

The outcome results of the inspection are positive as noted in the returned Form FDA 3274 (See Attachment #I). This was signed by S. Ferguson on 10/1/93.

**PREVIOUS REVIEW STATUS**

It is necessary to indicate that the initial CMC review dated 7/8/94 of this S-041 recommended an approval action pending satisfactory completion of the inspection at the proposed site. In this regard, this review constitutes an evaluative update.

**Appears This Way  
On Original**

6 Page(s) Withheld

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

     § 552(b)(5) Deliberative Process

     § 552(b)(4) Draft Labeling