CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-998/S051

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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-051

Trade Name: Vasotec

Generic Name(s): (enalapril maleate)

Sponsor: Merck Research Laboratories

Agent:

Approval Date: January 9, 1997

Indication: The treatment of hypertension.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-051

Approval Letter(s)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-998/S-051

JAN 9 1997

Merck Research Laboratories
Attention: Larry P. Bell, M.D.
P.O. Box 4, BLA-20
West Point, PA 19486

Dear Dr. Bell:

Please refer to your October 22, 1996 supplemental new drug application (NDA) 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 the use of Merck Manufacturing Division facilities in Arecibo, Puerto Rico for production of Vasotec 10 mg Tablets.

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,

1/9/97

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

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 18-998/S-051

Chemistry Review(s)

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 18-998
3. Name and Address of Applicant (City & State) Merck Research Laboratories West Point, PA 19486		4. Supplement(s) Number(s) Date(s) SCM-051 10/22/96
5. Drug Name Vasotec	6. Nonproprietary Name Enalapril Maleate	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: The use of Merck Manufacturing Division facilities in Arecibo, Puerto Rico for production of VASOTEC 10 mg tablets.		
9. Pharmacological Category Antihyertensive	10. How Dispensed ☒ Rx ☐ OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 10 MG	
14. Chemical Name and Structure		15. Records/Reports Current ☐ Yes ☐ No Reviewed ☐ Yes ☐ No

16. Comments:

This supplemental NDA "Changes Being Effected" is to support the transfer of manufacturing operations for tablets Vasotec 10 mg from Merck facilities in Caguas, PR to Merck facilities in Arecibo, PR (SUPAC guidelines, IV. site changes C. level 3 changes - change in manufacturing site to a different campus). The composition, manufacturing procedure, and quality and scale up procedures are the same as those currently utilized at Caguas, PR. Differences in the [redacted] conditions and method of transfer at two sites have not made any quality difference in production of tablets of three lots. Firm has placed on stability the tablets produced at Arecibo and provided 3 months accelerated data.

(Continued on page 2)

17. Conclusions and Recommendations:

The information presented in this supplement is satisfactory. EE request was made on 11/04/96 and facilities have been inspected on 07/18/96 and are acceptable (dated 11/12/96). Approval letter is issued.

18. REVIEWER		
Name JV Advani	Signature	Date Completed 12/04/96

Distribution: ☒ Original Jacket ☒ Reviewer ☒ Division File ☒ CSO

Copy to: Dr. S. Zimmerman

12/14/96

5 Page(s) Withheld

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

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling