

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

**APPLICATION NUMBER
18-998/S-059**


Microbiology Review(s)

MAR 23 1999

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REVIEW FOR HFD-110
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY REVIEW STAFF

March 17, 1999

- A. 1. IND 
SPONSOR Merck
2. PRODUCT NAMES: Vasotec (Enalapril Maleate)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Oral Suspension; 0.625 mg/mL, 1.0 mg/mL, and 1.25 mg/mL
4. METHOD(S) OF STERILIZATION: N/A
5. PHARMACOLOGICAL CATEGORY: Angiotensin Converting Enzyme, Inhibitor
- B. 1. DATE OF INITIAL SUBMISSION:
2. RELATED DOCUMENTS:
3. ASSIGNED FOR REVIEW: March 15, 1999
- C. REMARKS: The drug product is an oral suspension of Vasotec for pediatric use. This review addresses the antimicrobial effectiveness testing of the drug product.

APPEARS THIS WAY
ON ORIGINAL

D. CONCLUSIONS: Clinical trials may proceed from the standpoint of product quality microbiology.

/S/

3-17-99

Bryan Riley, Ph.D.

BR

3/19/99

cc:

- Original IND
- HFD 110/Division File
- HFD 110/K. Bongiovanni
- HFD 110/S. Zimmerman
- HFD 805/Consult File
- HFD 805/B. Riley

Drafted by: B. Riley, 3/17/99
R/D initialed by: P. Cooney,

Redacted 1

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