CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
18-998/S-059

Chemistry Review(s)

MAR 24 Bongiovanni

DNDC#1 CHEMIST'S IND REVIEW #1 (HFD-110)

IND: [redacted] REVIEW DATE: 3/23/99 CHEMIST: Stuart Zimmerman
DRUG NAME: Vasotec
SPONSOR: Merck Research Laboratories
DOC.DATE: 12/12/98-SN187, 1/12/99-SN188, 3/10/99-SN 195 & 3/12/99- SN196: CDER DATES:1/5-19, 3/11/99 & 3/16/99
DOSAGE FORM & STRENGTH: (see 12/28/98; SN 187 submission)

- Enalapril Maleate Tablets, 2.5 mg, 5 mg, 10 mg & 20 mg
- Placebo for Enalapril Maleate Tablets, 2.5 mg, 5 mg, 10 mg & 20 mg
- Enalapril Maleate Oral Suspension, 0.625 mg/mL, 1.0 mg/mL & 1.25 mg/mL
- Placebo Suspension for Enalapril Maleate Oral Suspension

ROUTE OF ADMIN: Oral
SPECIAL PRODUCTS: YES __ NO ___.
(If yes, fill out the form for special products and deliver to TIA through team leader for data entry)
PLACEBO: YES X

II. Manufacturer: Merck Laboratories

A. Drug Substance - see table below B .Drug Product - see table below

III. REVIEW

	Adequate Information Provided:			
	DRUG SUBSTANCE		DRUG PRODUCT	
TTRIBUTE/METHODS	YES (Vol, Page)	NO (Vol, Page)	YES (Vol, Page)	NO (Vol, Page)
nthesis/Manufacturing	Yes (no change)		Yes (SN-188)	
Identity	Yes (no change)		Yes (SN-188)	
Purity Profile	Yes (no change)		Yes (SN-188)	
Strength: see above statements			See above	
FOR PARENTERAL DRUG PRODUCTS:			NA	NA
Aseptic Fill Procedure			NA	NA
Terminal Sterilization			NA	NA
Sterility Test (USP or equiv.)			NA	NA
Pyrogen/Endotoxin Test (USP/FDA)			NA	NA
Other (sterility monitoring, particulates,etc.)			NA	NA

Attachments: (photocopies)
Drug substance specifications & structure Yes__ NoX (no change from NDA).
Components/Composition of Drug Product YesX No___.
Drug Product Specifications YesX No___.
Container/Closure (non-oral dosage form only) NA Yes__ No___.
Recommendation: Based on the information provided, it is reasonably safe to initiate clinical studies. YesX No
Additional Comments: This is a review of the information that the sponsor has provided to qualify the various dosage forms to be used in the protocol dealing with the Phase IV pediatric exclusivity study.
DRAFT PORTION OF LETTER ATTACHED: YES_____ NO X /NA .

CC: [redacted] (HFD-110)
FD-110//Division File
FD-110/SZimmerman
HFD-110//PM/KBongiovanni

/S/
Stuart Zimmerman

/S/
Team Leader

3-24-99

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commercial

information