

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-558/S-043

Chemistry Review(s)

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110/810	2. NDA Number 19-558
3. Name and Address of Applicant (City & State) Merck & Co. Inc. P.O. Box 4, BLA-20 West Point PA 19486		4. Supplement(s) Number(s) Date(s) SE5-043 9/24/01	
5. Drug Name Prinivil	6. Nonproprietary Name lisinopril	Amendments - Dates	
8. Supplement Provides For a request for a pediatric exclusivity determination			
9. Pharmacological Category Angiotensin converting enzyme Inhibitor:	10. How Dispensed Rx	11. Related NDAs The NDA 19-777/S-034 dated 11/02/01 deals with a similar type of change.	
12. Dosage Form(s) TCM	13. Potencies 2.5, 5, 10, 20, 40mg		
14. Chemical Name and Structure <small>PRINIVIL® (Lisinopril), a synthetic peptide derivative, is an oral long-acting angiotensin converting enzyme inhibitor. Lisinopril is chemically described as (S)-1-[(2S)-1-carboxy-3-phenylpropan-1-yl]-proline dihydrate. Its empirical formula is C₂₁H₃₁N₃O₇·2H₂O and its structural formula is</small>		15. Records/Reports Current Yes X No Reviewed Yes X No	
16. Comments: This supplement deals with an alternate suspension drug product formulation for use in hypertensive pediatric patients. The consult reviewer, Bryan Riley, recommends approval in his review dated 7/11/02 for the microbiological data submitted in support of this supplement. This review is <u> </u> The related submission for NDA 19-777/S-044(11/02/01). FILE: NNNSE5-043(9-24-01)TOKS			
17. Conclusions and Recommendations: This supplement may be approved from the standpoint of chemistry and manufacturing controls.			
18. REVIEWER			
Name Stuart Zimmerman,	Signature	Date Completed 7/11/02	

12 Page(s) Withheld

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

☐ § 552(b)(5) Deliberative Process

☐ § 552(b)(5) Draft Labeling

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/s/

Stuart Zimmerman
7/11/02 04:41:36 PM
CHEMIST

Kasturi Srinivasachar
7/11/02 04:59:06 PM
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