

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S2

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW (If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)		1. ORGANIZATION HFD-110	2. NDA NUMBER 19-777
3. NAME AND ADDRESS OF APPLICANT (City and State) Stuart Pharmaceuticals ICI Americas Inc. Wilmington, DE 19897		4. AF NUMBER 7-612	
		5. SUPPLEMENT (S)	
		NUMBER(S)	DATE(S)
6. NAME OF DRUG Zestril Tablets	7. NONPROPRIETARY NAME Lisinopril	S002	9/9/88
8. SUPPLEMENT(S) PROVIDES FOR: blister packaging update.		9. AMENDMENTS AND OTHER (Reports, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Antihypertensive	11. HOW DISPENSED ☒ RX ☐ OTC	12. RELATED IND/NDA/DMF(S)	
13. DOSAGE FORM (S) TCM	14. POTENCY (ies) 5, 10 and 20 mg		
15. CHEMICAL NAME AND STRUCTURE		16. RECORDS AND REPORTS	
		CURRENT ☐ YES ☐ NO	
		REVIEWED ☐ YES ☐ NO	
17. COMMENTS			
18. CONCLUSIONS AND RECOMMENDATIONS APPROVAL IS RECOMMENDED.			
19. REVIEWER NAME James H. Short			
DISTRIBUTION ☒ ORIGINAL JACKET		DATE COMPLETED SEP 16 1988	
REVIEWER ☒ /S/		DIVISION FILE ☐	