


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S6

CHEMISTRY REVIEW(S)

SEP - 5 1989

CHEMIST'S REVIEW <i>(If necessary, continue any item on 8" x 10 1/2" paper. Key continuation to item by number.)</i>		1. ORGANIZATION HFD-110		2. NDA NUMBER 19-777	
3. NAME AND ADDRESS OF APPLICANT (City and State) ICI Pharmaceuticals Group 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		S006	8/24/89
8. SUPPLEMENT(S) PROVIDES FOR: rework procedure for 40 mg tablets.				9. AMENDMENTS AND OTHER (Reports, etc.) DATES Y001 7/25/89	
10. PHARMACOLOGICAL CATEGORY Antihypertensive		11. HOW DISPENSED <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S) NDA 19-558	
13. DOSAGE FORM (S) TCM		14. POTENCY (See) 5, 10, 20 and 40 mg			
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS AND REPORTS	
				CURRENT <input type="checkbox"/> YES <input type="checkbox"/> NO	
				REVIEWED <input type="checkbox"/> YES <input type="checkbox"/> NO	
17. COMMENTS					
18. CONCLUSIONS AND RECOMMENDATIONS APPROVAL is recommended for the supplement. The information presented in the report is satisfactory, but some typos have been noted in the labels, and these should be brought to the attention of the firm.					
19. REVIEWER					
NAME James H. Short				DATE COMPLETED AUG 29 1989	
DISTRIBUTION		<input checked="" type="checkbox"/> ORIGINAL JACKET		<input type="checkbox"/> REVIEWER	
				<input type="checkbox"/> DIVISION FILE	

FORM FDH 2266 (7/75)

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

1

HFD-110/CSO

9/5/89

for 8/20/89