

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S8

CHEMISTRY REVIEW(S)

NOV 9 1990

CHEMIST'S REVIEW		1. Organization HFD-110	2. NDA Number 19-777
3. Name and Address of Applicant (City & State) ICI Pharmaceuticals Group Wilmington, DE 19897		4. AF Number 7-612	5. Supplement(s) Number(s) Date(s) S008 2/14/90
6. Name of Drug Zestril	7. Nonproprietary Name Lisinopril	9. Amendments & Other (Reports, etc) Dates amend 7/20/90 amend 9/26/90 amend 10/8/90	
8. Supplement(s) Provides For: The amendment of 10/8/90 provides a response to the Agency's letter of 9/18/90 requesting an EA from []			
10. Pharmacological Category Antihypertensive	11. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. Related IND/NDA/DMF N 19-558 (Prinivil Merck)	
13. Dosage Form(s) TCM	14. Potency(ies) 5, 10, 20 and 40 mg		
15. Chemical Name and Structure		16. Records & Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No	
17. Comments The amendment of 9/26/90 acknowledges receipt of our letter of 9/18/90, and states that a response is being prepared. The amendment of 10/8/90 consists of an EA from ICI concerning [] the manufacturer of TFA-lisinopril ester, a key intermediate used by ICI in manufacturing lisinopril drug substance. The EA is in the form required by 21 CFR 25.31a, as we requested.			
18. Conclusions and Recommendations: APPROVAL IS RECOMMENDED.			
19. REVIEWER			
Name James H. Short		Signature /S/	Date Completed 11/08/90
<input checked="" type="checkbox"/> Original Jacket		<input type="checkbox"/> Reviewer	<input type="checkbox"/> Div. File <input type="checkbox"/> CSO

jhs/11/8/90/N19-777.S08

1990

CHEMIST'S REVIEW		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	
6. NAME OF DRUG Zestril Tablets				5. SUPPLEMENT(S) NUMBER(S) DATE(S)	
				S-008 2/14/90	
7. NONPROPRIETARY NAME Lisinopril				9. AMENDMENTS AND OTHER DATES	
8. SUPPLEMENTS(S) PROVIDES FOR: an alternate pivotal intermediate for the synthesis of lisinopril dihydrate.					
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 DMF	
13. DOSAGE FORM(S) TCM		14. POTENCY(IES) 5, 10, 20 and 40 mg			
15. CHEMICAL NAME AND STRUCTURE				16. RECORDS/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 NOT APPROVABLE The deficiencies noted below will be conveyed to the applicant.					
19. REVIEWER					
NAME James H. Short		SIGNATURE /S/		DATE COMPLETED 3/19/90	
DISTRIBUTION jhs/3/7/90/0098X		ORIGINAL JACKET		REVIEWER DIVISION FILE CSO	
R/D init: RWalters/3/21/90					

Walters
3/21/90

SEP 18 1990

CHEMIST'S REVIEW		1. Organisation HFD-110	2. NDA Number 19-777
3. Name and Address of Applicant (City & State) ICI Pharmaceuticals Group Wilmington, DE 19897		4. AF Number 7-612	5. Supplement(s) Number(s) S008
			Date(s) 2/14/90
6. Name of Drug Zestril	7. Nonproprietary Name Lisinopril	9. Amendments & Other (Reports, etc) Dates amend 7/20/90	
8. Supplement(s) Provides For: The amendment provides responses to the Agency's letter of 3/21/90.			
10. Pharmacological Category Antihypertensive	11. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	12. Related IND/NDA/DMF N 19-558 (Prinivil Merck)	
13. Dosage Form(s) TCM	14. Potency(ies) 5, 10, 20 and 40 mg		
15. Chemical Name and Structure		16. Records & 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: Not approvable.			
19. REVIEWER			
Name James H. Short	Sig <i>/S/</i>	Date Completed 09/17/90	
<input checked="" type="checkbox"/> Original Jacket <input checked="" type="checkbox"/> Reviewer <input type="checkbox"/> Div. File <input type="checkbox"/> CSO			

Rev. 2/80
9/18/90