## **CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19777/S8** 

## **CHEMISTRY REVIEW(S)**

	CHEMIST'S REVIEW		1. Organisation	12. NDA Number						
			HFD-110	19-777   4. AF Number						
3.	Name and Address of Applica	e and Address of Applicant (City & State)								
	ICI Pharmaceuticals Group		• •	7-612 5. Supplement(s)						
	Wilmington, DE 19897		· · · · · · · · · · · · · · · · · · ·	Number(s) Date(s)						
			A.	S008 2/14/90						
6.	Name of Drug		nproprietary Name	9. Amendments & Other						
	Zestril		sinopril	(Reports, etc) Dates						
<u> </u>										
8.	Supplement(s) Provides For:	1		amend 7/20/90 amend 9/26/90						
	The amendment of 10/8/90 pr			amend 10/8/90						
	the Agency's letter of 9/18									
	from									
10.	Pharmacological Category		11. How Dispensed	12. Related IND/NDA/DMF						
	Antihypertensive	į	/X/ RX / / OTC	N 19-558 (Prinivil						
<u> </u>				Merck)						
13.	Dosage Form(s)	;	14. Potency (ies)							
	TCM		5, 10, 20 and	40 mg						
15.	Chemical Name and Structur	re		16. Records & Reports						
				Current						
				// Yes // No Reviewed						
1				// Yes // No						
<b> </b>										
1.	The amendment of 9/26/90 acknowledges receipt of our letter of 9/18/90, and states that a response is being prepared.									
1	The amendment of 10/8/90 c	consis	ts of an EA from IC	T concerning						
A	) the	e manui	facturer of TFA-lis:	inopril ester, a key						
	intermediate used by ICI i	in manu	ufacturing lisinopr:	il drug substance. The						
	EA is in the form required	1 by 2.	1 CFR 25.31a, as we	requested.						
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18.	Conclusions and Recommenda	ations	:							
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	APPROVAL IS RECOMMENDED.		and the second s							
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1			***							
<u> 19.</u>		REVI								
Nam	James H. Short	•	/S/ !	Date Completed 11/08/90						
<b>/</b>	James n. Short	<u>.</u>	/ <del>-</del>	11/09/30						

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3. NAME AND ADDRESS OF APPLIC	CANT (City			4. AF NUMI		
ICI Pharmaceuticals Group		,,		7-612		
Wilmington, DE 19897	-		•	5. SUPPLEMENT(S)		
	• •		•	NUMBER(S)		
6. NAME OF DRUG	7. NONPI	ROPRIETARY NAM	IE .			
W 17.23 W. W. 1 W	1			S-008	2/14/90	
Zestril Tablets	Lisi	nopril				
8. SUPPLEMENTS(S) PROVIDES FO	<u>, , , , , , , , , , , , , , , , , , , </u>			<b>}</b>		
· SOFF EEMENTS(S) FROVIDES FC	<i>,</i> , , , , , , , , , , , , , , , , , ,					
an alternate pivotal inter	mediate 1	for the synthe	sis of	9. AMENDME	NTS AND	
lisinopril dihydrate.		•		OTHER D		
				· -		
10. PHARMACOLOGICAL CATEGORY		1 HOLL BYCEFU	A=B			
Antihypertensive		1. HOW DISPEN	2FD	12. RELATE		
Antinyper tensive		IX I Rx	I <sup>—</sup> I отс	NDA/DM	1F(S)	
13. DOSAGE FORM(S)	114. POTE		1 1010	NDA 19	_558	
TCM	1	0, 20 and 40	ma	DMF		
		•				
15. CHEMICAL NAME AND STRUCTU	RE			16 RECORDS	/REPORTS	
•				C <u>URR</u> ENT _	<del></del>	
·	•		4	YES I	NO	
				R <u>EVI</u> EWED _     YES	i no	
17. COMMENTS				1 1 153 1	I NO	
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8. CONCLUSIONS AND RECOMMENDA	ATIONS					
NOT ADDROVED T	-				. ]	
NOT APPROVABLE						
The deficiencies noted be	low will i	ha conveyed to	. 469			
The delicities hoted be		ve -conveyed to	the appl	icant.		
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9.		/IFWER	4			
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James H. Short ISTRIBUTION   * ORIGINAL J	ACKET I	LACUTEUED 1	Interes		9/90	
15/3/7/90/0098X	MUNEI	REVIEWER	DIVISIO		CSO	
			_R/D init	: RWolters	/3/21/90	

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3. Name and Address of Applicant (City & State)  ICI Pharmaceuticals Group Wilmington, DE 19897  6. Name of Drug Zestril  7. Nonproprietary Name Lisinopril  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 IX/ RX / 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 // Yes // No Reviewed // Yes // No  17. Comments  18. Conclusions and Recommendations: Not approvable.	CHEMIST'S REVIEW	1. Organisation HFD-110	2. NDA Number 19-777						
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Name   Sign   Date Completed   O9/17/90	· · · · · · · · · · · · · · · · · · ·	, <del></del>							
James H. Short   09/17/90	19.								
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