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APPLICATION NUMBER: NDA 19777/S13

CHEMISTRY REVIEW(S)

141

FEB 27 1992

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. Supplement(s) Number(s) Date(s) S-013 1/8/92	
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril		7. Amendments & Other (reports, etc) - Dates 2/19/92
8. Supplement Provides For: A change in shape for the 5 mg tablet.			
9. Pharmacological Category Antihypertensive	10. How Dispensed <input type="checkbox"/> Rx <input type="checkbox"/> OTC		11. Related IND(s)/NDA(s)/DMF(s) NDA 19-558 Prinivil, Merck
12. Dosage Form(s) TCM	13. Potency(ies) 5, 10, 20, 40 mg		
14. Chemical Name and Structure			15. Records/Reports Current <input type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input type="checkbox"/> Yes <input type="checkbox"/> No
16. Comments: In reviewing this supplement I found several points that were unclear. I discussed these matters with Kevin McKenna on 2/5, 2/6 and 2/7/92. He agreed to provide his responses in writing, and this information was submitted in the amendment of 2/19/92. The supplement provides for a change in the shape of the 5 mg tablet to better distinguish between the 5 and 10 mg tablets. The shape will be changed from a round, biconvex, pink, bisected tablet to a capsule-shaped, biconvex, pink, bisected tablet. The qualitative and quantitative formulations and manufacturing directions for the new capsule shaped tablet are unchanged from those for the round tablet.			
17. Conclusions and Recommendations: APPROVAL is recommended for this supplement for capsule shaped tablets intagliated "ZESTRIL."			
18.		REVIEWER	
Name James H. Short		Date Completed 2/10/92	
Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

jhs/2/5/92/N19-777.S13
Revised 2/26/92

MS/
2-27-92

R/D init.: RWolters/2/11/92