

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S27

CHEMISTRY REVIEW(S)

JUL 11 1995

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110	2. NDA Number 19-777
3. Name and Address of Applicant (City & State) Zeneca Pharmaceuticals Wilmington, DE 19897		4. Supplement(s) Number(s) Date(s) S-027 6 Jun 95	
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates Y-007 26 Jun 95	
8. Supplement Provides For: A new bulk container/closure system for Zestril tablets.			
9. Pharmacological Category Antihypertensive	10. How Dispensed <input checked="" 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) 2.5, 5, 10, 20, 40 mg		
14. Chemical Name and Structure		15. Records/Reports Current <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
16. Comments: The new container/closure system consists of double LDPE bags contained in a gal fiber drum with a metal lid and closed with a metal Lok Rim. The LDPE bag is 26" wide x 36" high and is 0.003" thick. The resin contains neither BHT nor antioxidants. A letter of certification must be received with each shipment, and must contain the following information: 1. Purchase order number 2. IPR PCC number 3. Manufacturer's lot number 4. Statement indicating thickness of bag 5. Statement that material is BHT and antioxidant free. 6. Letter must be signed and dated by a responsible person.			
17. Conclusions and Recommendations: APPROVAL is recommended for the supplement. The information in the report is satisfactory. No reply is deemed necessary.			
18.			
Name James H. Short		REVIEWER <i>ISI</i>	Date Completed 10 Jul 95
Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO <input type="checkbox"/> District			

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R/D Init: RWalters/7/11/95

J. Short
7/11/95