

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S31

CHEMISTRY REVIEW(S)

OCT 11 1996

CHEMIST'S REVIEW		1. ORGANIZATION HFD-110	2. NDA Number, 19-777
3. Name and Address of Applicant (City & State) Zeneca Pharmaceuticals Wilmington, DE 19850-5437		4. Supplement(s) - Number(s) Date(s) S-031 18 Jun 96	
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates Amendment 25 Jun 96 SNC 25 Jun 96 SNC 19 Jul 96 SNC 29 Jul 96 Amendment 10 Sep 96	
8. Supplement Provides For: Use of tamper-evident induction seals on the containers used to package the drug product.			
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 correspondence dated 25 Jun 96 summarizes the points discussed between Robert Castor, Norbert Ealer and Louis Kovach from Zeneca and myself in my office on 19 Jun 96. The use of the proposed induction seals, subject of this supplement, was one of the topics discussed. The amendment of 25 Jun 96 provides details of the stability matrix proposed in support of the implementation of the tamper-evident seal as proposed in the supplement. The correspondence dated 19 Jul 96 provides a Letter of Authorization (LoFA) from allowing the Agency to review DMF The correspondence dated 29 Jul 96 provides a modified stability matrix. The amendment of 10 Sep 96 provides the applicants's acceptance specifications for the closure.			
17. Conclusions and Recommendations: APPROVAL is recommended.			
18.			
Name James H. Short		Date Completed 10 Sep 96	
Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

jhs/6/24/96/N19-777.S31

R/D Init: RWalters/9/11/96

JHS
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10/11/96