CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S30

CHEMISTRY REVIEW(S)

NOV 2 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 19850-5437		4. Supplement(s) Number(s) Date(s) S-030 20 Oct 95
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates
8. Supplement Provides For: Final Printed Labeling (FPL) for a revised Package Insert (PI).		
9. Pharmacological Category Antihypertensive	10. How Dispensed [X] Rx [ ] 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 [X] Yes [ ] No Reviewed [X] Yes [ ] No

16. Comments:

Changes have been made in the following sections: Adverse Reactions - Skin, Description and How Supplied.

The Description and How Supplied sections have been revised to provide for marketing the 2.5 mg tablet which was approved in S-016.

I do not understand why the statement "Zestril 2.5 mg tablets are manufactured by Zeneca Pharmaceuticals." is included in the How Supplied section, since this statement is not repeated for the other strengths. I believe it should be deleted.

The revised PI is designated "Rev F 09/95."

17. Conclusions and Recommendations:

APPROVABLE in regard to the technical aspects of the labeling, with the one change suggested above.

18. 1ST REVIEWER

Name James H.Short

Date Completed 30 Oct 95

Distribution:

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jhs/10/30/95/N19-777.S30

R/D Init: RWolters/10/31/95

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