# CENTER FOR DRUG EVALUATION AND RESEARCH

## APPLICATION NUMBER: NDA 19777/S11

## CHEMISTRY REVIEW(S)

JUL 29 1991

| 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) S011 Date(s) 7/18/91 |
| 5. Drug Name Zestril | 6. Nonproprietary Name Lisinopril | 7. Amendments & Other (reports, etc) - Dates Y003 7/1/91 |
| 8. Supplement Provides For: Rework procedure involving material more than one year old. | | |
| 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) 5, 10, 20, 40 mg | |
| 14. Chemical Name and Structure | | 15. Records/Reports Current [X] Yes [ ] No Reviewed [X] Yes [ ] No |

16. Comments:

The supplement requests approval to market two lots of 10 mg tablets which were manufactured using reworked material over one year old.

S003, approved 1/18/89, provides for rework of 10 and 20 mg tablets, providing that such rework lots contain no more than % nonvirgin material. Further, such nonvirgin material may not be more than one year old.

In September 1990, the applicant prepared a granulation (Lot 1215K) of nonvirgin material to be included in rework tablets. The granulation weighed kg. The oldest component of this batch was regrind material from tablets manufactured in March, 1990 (Lot 9016K). This material should have been assigned a "do not use after" date of March 1991. Instead the date assigned was June 1991. This batch of regrind material weighed kg, thus comprising % of Lot 1215K.

17. Conclusions and Recommendations:

APPROVAL is recommended for the supplement.

The information presented in Y003 is satisfactory.

18. REVIEWER /S/

Name James H.Short Date Completed 7/23/91

Distribution: [X] Original Jacket [ ] Reviewer [ ] Division File [ ] CSO

jhs/7/19/91/N19-777.S11 R/D init.: RWolters/7/24/91