CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S17

CHEMISTRY REVIEW(S)

MAY 26 1993

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110	2. NDA Number 19-777

3. Name and Address of Applicant (City & State) Zeneca Inc. Wilmington, DE 19897	4. Supplement(s) Number(s) Date(s) S-017 12 Feb 93

| 5. Drug Name Zestril | 6. Nonproprietary Name Lisinopril | 7. Amendments & Other (reports, etc) - Dates

Amendment   13 Apr 93 |
|---|---|---|

8. Supplement Provides For:
Manufacture of 5, 10, 20 and 40 mg Zestril Tablets by IPR Pharmaceuticals, Inc., Carolinas, PR, a division of Zeneca, Ltd. (UK).

| 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:

The amendment provides responses to the deficiencies noted in the review of the original submission and conveyed to the applicant in a letter dated 1 Apr 93. The deficiencies are repeated followed by the applicant's responses.

An approved EER was received from HFD-320 dated 5 May 93.

17. Conclusions and Recommendations:

The information provided by the applicant in response to the Agency's letter of 1 Apr 93 is satisfactory.

APPROVAL is recommended

18.

Name   James H.Short

/S/ REVIEWER

Date Completed

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

jhs/5/21/93/N19-777A.S17

R/D Init: RWolters/5/26/93

CHEMIST'S REVIEW	1. ORGANIZATION HFD-110·	2. NDA Number 19-777

3. Name and Address of Applicant (City & State)
Zeneca Inc.
Wilmington, DE 19897

4. Supplement(s)
- Number(s)   Date(s)
  S-017   12 Feb 93

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14. Chemical Name and Structure

15. Records/Reports
Current
[x] Yes   ☐ No
Reviewed
[x] Yes   ☐ No

16. Comments:

17. Conclusions and Recommendations:

NOT APPROVABLE

The deficiencies noted in the review of this supplement will be conveyed to the applicant.

18.

Name   James H.Short

REVIEWER.
|S|

Date Completed   29 Mar 93

Distribution: ☐ Original Jacket ☐ Reviewer ☐ Division File ☐ CSO

jhs/3/22/93/N19-777.S17

R/D Init: RWolters/3/31/93