CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19777/S20

CHEMISTRY REVIEW(S)

S.020
6-30-93
CS.1

JUL 8 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) S-020 Date(s) 30 Jun 93
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates
8. Supplement Provides For: 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:

The supplement provides for additions to the Warnings section of the PI concerning anaphylactoid reactions as requested in the Agency's letter of 17 Feb 93.

No changes are proposed for the Description and How Supplied sections.

The revision number is Rev Q 04/93.

17. Conclusions and Recommendations:

APPROVABLE

The technical aspects of the labeling are unchanged and remain satisfactory.

18. REVIEWER

Name James H.Short /S/ Date Completed 6 Jul 93

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R/D Init: RWolters/7/7/93

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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-020 30 Jun 93
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates Amendment 21 Jun 94 Y-006 10 Jun 94
8. Supplement Provides For: 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:

The supplement provides for additions to the Warnings section of the PI concerning anaphylactoid reactions as requested in the Agency's letter of 23 Sep 93. However, in the amendment, the applicant has proposed alternate language to that recommended by the Agency.

No changes are proposed for the Description and How Supplied sections, except as noted below, which remain satisfactory.

The revision number is Rev Q 04/93.

17. Conclusions and Recommendations:

APPROVABLE

The 40 mg HUD configuration has been deleted from the How Supplied section. The technical aspects of the labeling remain satisfactory, except that "Zestril," the first word in the Description section of the PI, should be changed to "Lisinopril" at the next printing.

18. REVIEWER

Name James H.Short (S) Date Completed 28 Jun 94

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7-1-94

MAR 1 1995

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-020 30 Jun 93
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates Amendment 23 Feb 95
8. Supplement Provides For: 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) 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 for additions to the Warnings section of the PI concerning anaphylactoid reactions as requested in the Agency's letter of 17 Feb 93. The applicant also proposes changes in the Precautions, Cough, subsection.

The following change is proposed for the How Supplied section as requested in the Agency's letter of 2 Dec 94. "Zestril (lisinopril), a synthetic peptide derivative, is an oral long-acting angiotensin converting enzyme inhbitor. Lisinopril is chemically described as ... " is being revised to "Lisinopril is an oral long-acting angiotensin converting enzyme inhibitor. Lisinopril, a synthetic peptide derivative, is chemically described as ... ."

The revision number is Rev Z-3 02/95.

17. Conclusions and Recommendations:

APPROVABLE

The technical aspects of the labeling are satisfactory.

18. /S/ REVIEWER

Name James H.Short — Date Completed 28 Feb 95

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JUN 1 1995

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-020 30 Jun 93
5. Drug Name Zestril	6. Nonproprietary Name Lisinopril	7. Amendments & Other (reports, etc) - Dates Amendment 21 Jun 94 Amendment 23 Feb 95 Amendment 18 May 95
8. Supplement Provides For: 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) 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 of 18 May 95 provides FPL for additions to the Warnings section of the PI concerning anaphylactoid reactions as requested in the Agency's letter of 17 Feb 93, 23 Sep 93, and 5 Apr 95. The applicant also includes changes in the Precautions, Cough, subsection.

The following change has been made in the Description section as requested in the Agency's letter of 2 Dec 94. "Zestril (lisinopril), a synthetic peptide derivative, is an oral long-acting angiotensin converting enzyme inhibitor. Lisinopril is chemically described as ... " is being revised to "Lisinopril is an oral long-acting angiotensin converting enzyme inhibitor. Lisinopril, a synthetic peptide derivative, is chemically described as ... ."

The revision number is Rev B-1 04/95.

17. Conclusions and Recommendations:

APPROVABLE

The technical aspects of the labeling are satisfactory.

18. REVIEWER

Name James H.Short /S/ Date Completed 30 May 95

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