CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S24

APPROVAL LETTER

NDA 19-777/S-024

JUN 5 1995

Zeneca Pharmaceuticals Group
Attention: Robert Castor
1800 Concord Pike
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your November 18, 1994 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) 2.5, 10, 20 and 40 mg tablets.

The supplemental application provides for transfer of testing of the drug substance and drug product from the existing laboratories in Guayama and Carolina, PR to a new laboratory facility at the Guayama location.

We have completed the review of this supplemental application and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Sincerely yours,

6/5/95

Robert Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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APPLICATION NUMBER: NDA 19777/S24

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APPROVABLE LETTER

2811

NDA 19-777/S-024

MAY 15 1995

Zeneca Pharmaceuticals Group
Attention: Robert Castor
1800 Concord Pike
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your November 18, 1994 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) 2.5, 10, 20 and 40 mg tablets.

The supplemental application provides for transfer of testing of the drug substance and drug product from the existing laboratories in Guayama and Carolina, PR to a new laboratory facility at the Guayama location.

We have completed our review and find the information presented is inadequate, and the supplemental application is not approvable under section 505(b) of the Act and 21 CFR 314.125(b). The deficiencies may be summarized as follows:

The San Juan District Office has not approved your new facility since all of the equipment is not in place. Please notify us by telephone as soon as the equipment is in place. At that time, we will contact the San Juan District Office to ascertain if a follow-up to the initial inspection is needed.

Should you have any questions, please contact:

Kathleen Bongiovanni
Consumer Safety Officer
Telephone: (301) 594-5300

Sincerely yours,

5-15-95

Robert Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research