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Application Number: NDA 19777/S27

APPROVAL LETTER

NDA 19-777/S-027

Zeneca Pharmaceuticals
Attention: Robert Castor
P.O. Box 15437
Wilmington, DE 19897

JUL 11 1995

Dear Mr. Castor:

Please refer to your June 6, 1995 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 a new bulk container/closure system for Zestril tablets.

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,

7/11/95

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