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Application Number: NDA 19777/S30

APPROVAL LETTER

NDA 19-777/S-030

Food and Drug Administration
Rockville MD 20857

Zeneca Pharmaceuticals
Attention: W.J. Kennedy, Ph.D.
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

NOV 15 1995

Dear Dr. Kennedy:

We acknowledge receipt on October 23, 1995 of your October 20, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) 2.5, 5, 10, 20 and 40 mg Tablets.

The supplemental application provides for final printed labeling revised as follows:

DESCRIPTION: The third paragraph has been revised to include the 2.5 mg tablet strength and "2.5 mg tablets - calcium phosphate, magnesium stearate, mannitol, starch" has been added under **Inactive Ingredients**. These changes were previously approved on April 29, 1993, in supplement 016.

ADVERSE REACTIONS, Skin: "pemphigus" and "including Stevens-Johnson syndrome" have been added.

HOW SUPPLIED: Information on the 2.5 mg tablet has been added.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the October 20, 1995 final printed labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

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

If you have any questions, please contact:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

11/15/95

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research