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Application Number: NDA 19777/S26

APPROVAL LETTER

NDA 19-777/S-026
NDA 19-888/S-023

JUL 11 1995

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

Dear Mr. Castor:

Please refer to your June 6, 1995 supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) 2.5, 10, 20 and 40 mg tablets (NDA 19-777) and for Zestoretic (lisinopril/hydrochlorothiazide) 10/12.5, 20/12.5, and 20/25 mg tablets (NDA 19-888).

The supplemental applications provide for replacement of trichloroethane with a mixture of t-butyl methyl ether and methylcyclohexane in the manufacture of lisinopril TFA ester, the precursor of lisinopril drug substance.

We have completed the review of these supplemental applications and they are 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