CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S31

APPROVAL LETTER

OCT 11 1996

NDA 19-777/S-031
NDA 19-888/S-027

Zeneca Pharmaceuticals
Attention: Robert Castor
P.O. Box 15437
Wilmington, DE 19850-5437

Dear Mr. Castor:

Please refer to your June 18, 1996 supplemental new drug applications 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 (NDA 19-777) and for Zestoretic (lisinopril/hydrochlorothiazide) 10/12.5, 20/12.5 and 20/25 mg tablets (NDA 19-888).

We acknowledge receipt of your amendments dated June 25 (2), July 19, July 29, and September 10, 1996 for NDA 19-777 and June 25 (2) and September 10, 1996 for NDA 19-888.

The supplemental applications provide for use of tamper-evident induction seals on the containers used to package the drug product.

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,

10/11/96

Robert D Wolters, Ph.D.
Chemistry Team Leader, DNDC-1
Division of Cardio-Renal Drug Products (HFD-110)
Office of Drug Evaluation 1
Center for Drug Evaluation and Research