DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-777/S-037

Zeneca Pharmaceuticals
Attention: Mr. Anthony F. Rogers
1800 Concord Pike
P.O. Box 15437
Wilmington, DE 19850-5437

Dear Mr. Rogers:

Please refer to your supplemental new drug application dated January 29, 1999, received February 2, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) 2.5, 5, 10, 20, 30 and 40 mg Tablets.

We acknowledge receipt of your submissions dated December 13 and 30, 1999.

Your submission of December 30, 1999 constituted a complete response to our December 2, 1999 action letter.

This supplemental new drug application provides for changes in several sections of the package insert to incorporate statements concerning the use of high doses of lisinopril to reduce the risk of the combined outcomes of mortality and hospitalization in patients with congestive heart failure. These statements are based on the results of the "Assessment of Treatment with Lisinopril and Survival (ATLAS)" study.

We have completed the review of this supplemental new drug application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed labeling included in your December 30, 1999 submission. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call:

Ms. Sandra L. Birdsong
Regulatory Project Manager
(301) 594-5312

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research