NDA 19-777/S-017

20.1
S-017
4-13-93

Zeneca Pharmaceuticals Group
Attention: Robert Castor
1800 Concord Pike
Wilmington, DE 19897

MAY 26 1993

Dear Mr. Castor:

Please refer to your February 12, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) Tablets.

We also acknowledge receipt of your amendment dated April 13, 1993.

The supplemental application provides for manufacturing and packaging of Zestril Tablets by IPR Pharmaceuticals, Inc., Carolinas, PR.

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,

5/26/93

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

cc:
Original NDA
HFC-130/JAllen
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-730
HFD-110/JShort/5/21/93
clb/5/26/93/N19777.S17

JKShort 5/26/93

Approval Date: 19 May 1988

APPROVAL