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Application Number: NDA 19777/S8

APPROVAL LETTER

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101-11.1

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NDA 19-777/S-008

ICI Pharmaceuticals Group
Attention: Kevin McKenna, Ph.D.
Wilmington, DE 19897

Dear Dr. McKenna:

Please refer to your February 14, 1990 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 amendments dated July 20, 1990, September 26, 1990 and October 8, 1990.

The supplemental application provides for the manufacture of TFA-lisinopril ester by []

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,

JS/ 11/9/90

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
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-730
HFD-110/JShort/11/8/90
clb/11/9/90/3316C

JK 11/9/90

Approval Date: November 9, 1990

APPROVAL