CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S13

APPROVAL LETTER

NDA 19-777/S-013

ICI Pharmaceuticals Group
Attention: Mr. Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your January 8, 1992 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril) Tablets.

The supplemental application provides for a change in shape for the 5 mg tablet from a round tablet to a capsule-shaped tablet.

We have completed the review of this supplemental application and it is approved for manufacture of a 5 mg capsule-shaped tablet intagliated "ZESTRIL."

If you wish to market a 5 mg tablet intagliated "STUART," you will need to submit another supplement containing comparative dissolution data to support this change.

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,

2/12/92

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/2/10/92
clb/2/11/92/N19777.S13
R/D init: RWolters/2/11/92

2/12/92

Approval Date: May 19, 1988

APPROVAL