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Application Number: NDA 19777/S11

APPROVAL LETTER

JUL 29 199

NDA 19-777/S-011

ICI Pharmaceuticals Group
Attention: Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your July 18, 1991 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 one-time variance in the rework procedure for the drug product.

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,

7/29/91

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:
NWK-DO
~~Original NDA~~ 7/25/91
HFD-110
HFD-110/CSO
HFD-80/DDIR
HFD-100
HFD-730
HFD-110/JShort/7/23/91
sh/7/24/91;7/25/91:0266H
R/D init: RWolters/7/24/91

Approval Date: May 19, 1988

APPROVAL