

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S6

APPROVAL LETTER

NDA 19-777/S-006

SEP - 5 1989

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

Dear Mr. Castor:

Please refer to your August 24, 1989 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 rework procedure for 40 mg tablets.

We have completed the review of this supplemental application and it is approved. Our letter of May 19, 1988 detailed the conditions relating to the approval of this application.

We do not object to your one-time request to reprocess material older than one year.

We understand that stability studies will be carried out on the first lot of tablets prepared by this rework procedure.

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,

Q15189

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/8/29/89

clb/8/30/89/1685C

R/D init: AThompson/8/30/89

JWS 8/30/89

APPROVAL