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Application Number: NDA 19777/S15

APPROVAL LETTER

NDA 19-777/S-015
19-888/S-010

NOV 18 1992

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

Dear Dr. McKenna:

Please refer to your May 15, 1992 supplemental new drug applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (lisinopril, NDA 19-777) and Zestoretic (lisinopril/hydrochlorothiazide, NDA 19-888) Tablets.

We also acknowledge receipt of your amendments dated August 31, 1992.

The supplemental applications provide for manufacture of lisinopril dihydrate at your Macclesfield, Cheshire, U.K. facility.

We have completed the review of these supplemental applications and they are approved.

We ask that you submit a DMF for your Macclesfield plant since the Agency still requires DMFs for foreign firms, and it will be helpful for future inspections.

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,

11/18/92

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