

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Application Number: NDA 19777/S12**

**APPROVAL LETTER**

~~NDA 19-777/S-012~~  
19-888/S-008

DEC 11 1991

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

Dear Dr. McKenna:

Please refer to your October 8, 1991 supplemental new drug applications submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Zestril (NDA 19-777) and Zestoretic (NDA 19-888).

We also acknowledge receipt of your amendment dated December 2, 1991.

The supplemental applications provide for the contact manufacture of two intermediates for the synthesis of lisinopril.

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

12-11-91

u

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/12/6/91  
clb/12/9/91/lisinopr.ltr

JAS 12/10/91

Approval Date: 5/19/88 (NDA 19-777)  
7/20/89 (NDA 19-888)

APPROVAL