

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19777/S2

APPROVAL LETTER

SEP 20 1988

Stuart Pharmaceuticals
Attention: Robert Castor
Wilmington, DE 19897

Dear Mr. Castor:

Please refer to your September 9, 1988 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 updating the components used in blister packaging.

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 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,

S 9/20/88

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-232 (with labeling)~~

HFD-730

HFD-110/JShort/9/16/88

clb/9/19/88/0992C

R/D init: RWolters/9/19/88

APPROVAL

MB 9/19/88