# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number: NDA 19787/S009**

## APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-787/S-009

DEC -5 1995

Pfizer, Inc.
Attention: Ms. Rita Wittich
235 East 42nd Street
New York, NY 10017

Dear Ms. Wittich:

Please refer to your August 14, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5, 5, and 10 mg Tablets.

The supplemental application provides for final printed labeling revised in response to our March 22, 1995 supplement request letter as follows:

**ADVERSE REACTIONS**:

The following has been inserted above the last paragraph:

> In the post-marketing experience, jaundice and hepatic enzyme elevations (mostly consistent with cholestasis) in some cases severe enough to require hospitalization have been reported in association with use of amlodipine.

For clarity, please insert commas around the clause "in some cases severe enough to require hospitalization" at the time of your next printing.

The following has been added to the formerly penultimate paragraph:

> No clinically relevant changes were noted in serum potassium, serum glucose, total triglycerides, total cholesterol, HDL cholesterol, uric acid, blood urea nitrogen, or creatinine.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the August 14, 1995 final printed labeling. Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit one market package of the drug when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

/S/ 12/5/95

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:
Original NDA
HF-2/MedWatch (with labeling)
HFD-80 (with labeling)
HFD-110
HFD-110/Project Manager
HFD-240 (with labeling)
HFD-613 (with labeling)
HFD-735/DBarash (with labeling)
HFD-110/KBongiovanni
sb/11/20/95;11/30/95
R/D: RMittal
RWolters/11/20/95
CResnick/11/20/95
KKnudsen/11/27/95
RFenichel/11/28/95
GBuehler for NMorgenstern/11/30/95

Approval Date: July 31, 1992

APPROVAL

NR 12-5-95