# CENTER FOR DRUG EVALUATION AND RESEARCH

**Application Number: NDA 19787/S003**

## APPROVAL LETTER

24.1

NDA 19-787/S-003

MAR = 8 1994

Pfizer Inc.
Attention: Inna Kissen, Ph.D.
235 East 42nd Street
New York, NY 10017-5955

Dear Dr. Kissen:

Please refer to your December 9, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate).

The supplemental application provides for the use of the expanded facility in Barceloneta, Puerto Rico, for the synthesis of amlodipine besylate, the drug substance used in the manufacture of Norvasc Tablets.

We have completed the review of this supplemental application and it is 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,

/S/ 3-3-94

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-83
HFD-110/RMittal/2/28/94
clb/3/1/94/N19787.S03

Approval Date: (19)_____

APPROVAL