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Application Number: NDA 19787/S005

APPROVAL LETTER

NDA 19-787/S-005

FEB - 7 1995

Pfizer, Inc.
Attention: Inna Kissen, Ph.D.
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Kissen:

Please refer to your October 25, 1994 supplemental new drug application submitted November 2, 1994 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for NORVASC (amlodipine besylate), 2.5 mg, 5.0 mg and 10.0 mg Tablets.

The supplemental application provides for as an additional alternate package site for 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/ 2-7-95

Robert 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
HFD-232
HFD-110/RMittal
clb/2/7/95/N19787.S05
R/D init: RWolters

Approval Date: 7/31/92

APPROVAL