CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S008

APPROVAL LETTER

NOV 2 1995

NDA 19-787/S-008

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

Dear Dr. Kissen:

Please refer to your August 3, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5 mg, 5 mg and 10 mg Tablets.

The supplemental application provides for the specification for the UK-55,410 content in Norvasc Tablets be changed from

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/ 11/2/95

Robert Wolters, Ph.D.
Supervisory Chemist
Division of New Drug Chemistry 1, Cardio-Renal
Office of New Drug Chemistry
Center for Drug Evaluation and Research