CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S014

APPROVAL LETTER

NDA 19-787/S-014

APR 18 1997

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

Dear Dr. Kissen:

Please refer to your December 12, 1996 supplemental new drug application (NDA) submitted under section 505(b) of the Federal Rood, Drug, and Cosmetic Act for Norvasc (amlodipine besylate), 2.5 mg, 5.0 mg, and 10.0 mg Tablets.

The supplemental application provides for a change in of the amlodipine besylate manufacturing process.

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

For your routine stability testing of the tablets, please indicate on your stability report the lots of tablets that were manufactured using this revised procedure.

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/ 4/18/97

Robert J. Wolters, Ph.D.
Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research