CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S011

APPROVAL LETTER

30.1

NDA 19-787/S-011

FEB - 7 1996

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

Dear Dr. Kissen:

Please refer to your January 22, 1996 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 approval of new facility for to package the drug product at .

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/ 2/7/96

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