CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S019

APPROVAL LETTER

SEP - 7 1999

NDA 19-787/S-019

Pfizer Inc.
Attention: Rita Wittich
235 East 42nd Street
New York, N.Y. 10017-5755

Dear Ms. Wittich:

Please refer to your supplemental new drug application (NDA) dated May 14, 1999, received May 17, 1999, submitted 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 packaging site for the drug product.

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/ 9-7-99

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products (HFD-110)
Office of New Drug Chemistry
Center for Drug Evaluation and Research