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Application Number: NDA 19787/S012

APPROVAL LETTER

32.1

NDA 19-787/S-012

JUN 28 1996

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

Dear Dr. Kissen:

Please refer to your March 29, 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, 5.0 mg and 10.0 mg Tablets.

The supplemental application provides for changes in of the currently approved manufacturing process.

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/ 6/28/96

Robert J. Wolters, Ph.D.
Chemistry Team Leader, DNDC-1
Division of Cardio-Renal Drug Products (HFD-110)
Office of Drug Evaluation 1
Center for Drug Evaluation and Research