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Application Number: NDA 19787/S015

APPROVAL LETTER

NDA 19-787/S-015

MAY 16 1997

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

Dear Dr. Kissen:

Please refer to your February 28, 1997 supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5, 5.0 and 10.0 mg Tablets.

The supplemental application provides for Pfizer's new organic synthesis building at your Groton Connecticut campus.

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/ 5/16/97

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