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Application Number: NDA 19787/S004

APPROVAL LETTER

NDA 19-787/S-004

MAY 3 1994

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

Dear Dr. Kissen:

Please refer to your April 12, 1994 supplemental new drug application submitted on April 20, 1994 under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) Tablets.

The supplemental application provides for the approval of a revised Process Monograph Description (PMD) for the drug substance amlodipine besylate. The PMD revision incorporates the following minor changes:

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,

/S/ 5-3-94

Robert J. Wolters, Ph.D.
Supervisory Chemist
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research