

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S006

APPROVAL LETTER

261

NDA 19-787/S-006

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

JUN 19 1995

Dear Dr. Kissen:

Please refer to your March 31, 1995 supplemental new drug application submitted on April 6, 1995 under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5, 5 and 10 mg Tablets.

The supplemental application provides for the replacement of particle size methodology

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,

RS/ 6/19/95

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

cc:

- Original NDA
- HFC-130/JAllen
- HFD-110
- HFD-110/CSO
- HFD-80
- HFD-110/RMittal
- clb/6/13/95/N19787.S06
- R/D init: RWolters

Approval Date: July 31, 1992

APPROVAL