CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-787/S-002

JAN 12 1995

U.S. Pharmaceuticals Group
Pfizer Inc.
Attention: John E. Wolleben, Ph.D.
235 East 42nd Street
New York, NY 10017-5755

Dear Dr. Wolleben:

We acknowledge your October 5, 1993 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) Tablets.

We also acknowledge receipt of your amendment dated September 7, 1994.

The supplemental application provides for final printed labeling revised under **ADVERSE REACTIONS** as follows:

> **"Cardiovascular:** arrhythmia" was expanded to read **"Cardiovascular:** arrhythmia (including ventricular tachycardia and atrial fibrillation), ..."
>
> Gingival hyperplasia was added under **Gastrointestinal.**
>
> The third from the last paragraph in this section as revised to read as follows:
>
> > Other reactions occurred sporadically and cannot be distinguished from concurrent medications or disease states such as myocardial infarction and angina.

We have completed the review of this supplemental application and it is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

Should you have any questions, please contact:

Mr. David Roeder
Consumer Safety Officer
Telephone: (301) 594-5300

Sincerely yours,

/S/ 1/12/95

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research