DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-787/S-042

Pfizer Inc.
Attention: Mr. Robert Clark
235 East 42nd Street
New York, NY 10017

Dear Mr. Clark:

Please refer to your April 26, 2007 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5, 5, and 10 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the introduction of generic Amlodipine Besylate 2.5, 5, and 10 mg Tablets for Greenstone Limited, a division of Pfizer, and proposed changes in packaging configurations and tablet counts for Norvasc (amlodipine besylate) Tablets, 2.5 mg, 5 mg and 10 mg and Amlodipine Besylate Tablets, 2.5 mg, 5 mg and 10 mg (Greenstone) drug products.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on April 26, 2007. We will transmit the SPL version of the labeling submitted on April 26, 2007 to the National Library of Medicine for public dissemination.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Denise Hinton, Regulatory Project Manager, at (301) 796-1090.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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