



NDA 19-787/S-032

Pfizer, Inc.  
Attention: Ms. Rita A. Wittich  
235 East 42<sup>nd</sup> Street  
New York, New York 10017

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated January 23, 2002, received January 24, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) Tablet, 2.5, 5.0, and 10 mg.

This "Changes Being Effected in 30 days" supplemental new drug application proposes the following changes:

1. Under **ADVERSE REACTIONS/General**, the words "weight decrease" has been added.
2. This entry has been changed from:

**General:** allergic reaction, asthenia, \*\*back pain, hot flushes, malaise, pain rigors, weight gain.

to

**General:** allergic reaction, asthenia, \*\*back pain, hot flushes, malaise, pain rigors, weight gain, weight decrease.

3. Under **How Supplied**, the NDC information has been updated as follows:
  - a. "NDC 0069-1520-66 Bottle of 100" has been deleted under Norvasc® 2.5 mg Tablets.
  - b. "NDC 0069-1530-66 Bottle of 100" has been deleted under Norvasc® 5 mg Tablets.
  - c. "NDC 0069-1540-41 Bottle of 100" has been deleted under Norvasc® 10 mg Tablets.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in the January 23, 2002 submission). Accordingly, the supplemental application 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.

If you have any questions, please call:

Denise M. Hinton  
Regulatory Project Manager  
(301) 594-5312

Sincerely,

*{See appended electronic signature page}*

Douglas C. Throckmorton  
Director  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research

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/s/

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Doug Throckmorton  
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