CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S019

CORRESPONDENCE

ORIGINAL

Regulatory Affairs Division
Pfizer Pharmaceuticals Group
Pfizer Inc
235 East 42nd Street
New York. NY 10017-5755
Tel 212 573 5999 Fax 212 733 6609

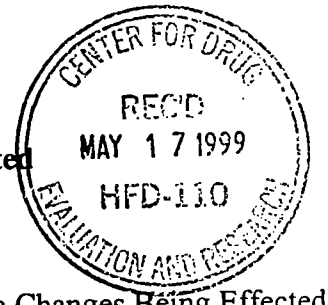
Pfizer Pharmaceuticals

Jean Lyons, MS
Director
Regulatory Affairs

May 14, 1999

NDA NO. 19-787 REF. NO. 019
NDA SUPPL FOR SCM

Raymond Lipicky, M.D., Director
Division of Cardio-Renal Drug Products (HFD-110)
Center for Drug Evaluation and Research
Office of Drug Evaluation I
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857



RE: Norvasc (amlodipine besylate) tablets
NDA # 19-787
Supplement: SUPAC-IR – Changes Being Effected

Dear Dr. Lipicky,

Pursuant to 21 CFR 314.70 (c), Pfizer Inc hereby submits a Changes Being Effected Supplement to NDA #19-787 (amlodipine besylate) tablets.

This is a Stand Alone Packaging Operations Site Change supplement that is based on the Scale-up and Post-Approval Changes Guidance for Immediate Release Products (SUPAC-IR), letter from FDA dated February 18, 1997 (copy included in Section 2 of this submission). The purpose of this supplement is to add
as an additional packaging site for the subject product.

Pursuant to the Guidance, the following information described in Overview, Section 1, is enclosed:

- Summary
- Additional Packaging Site Location
- cGMP Compliance Profile
- Stability Commitment and Protocol

Please be advised that Pfizer will implement this packaging operation site change on, or after June 15, 1999. Ongoing stability data for amlodipine besylate tablets packaged at
will be submitted in subsequent annual reports.

In accordance with 21 CFR 314.70 (a), a certified field copy of the submission is being submitted to the Brooklyn District office concurrently with the one to the Review Division.

If you have any questions, please contact the undersigned at (212)-573-5999.

Thank you very much for your assistance.

Sincerely,

Jean Lyons, M.S.
Director, Regulatory Affairs

Desk Copy: Mr. David Roeder