CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19787/S018

APPROVAL LETTER

JUN - 4 1999

NDA 19-787/ S-018

Pfizer Inc.
Attention: Rita Wittich
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Wittich:

Please refer to your supplemental new drug application dated April 14, 1999 received April 15, 1999 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norvasc (amlodipine besylate) 2.5 mg, 5 mg and 10 mg Tablets.

The supplemental application provides for the addition of your manufacturing facility at Parsippany, N.J. as a packaging site for the drug product.

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,

/S/ 6-4-99

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I, for the
Division of Cardio-Renal Drug Products, (HFD-110)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

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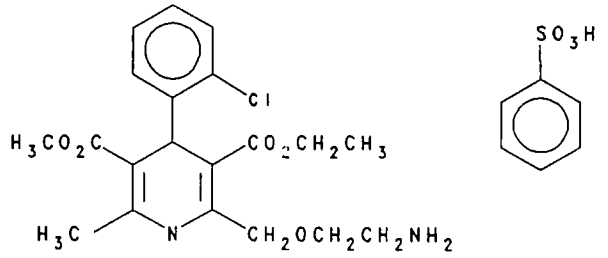
APPLICATION NUMBER: NDA 19787/S018

CHEMISTRY REVIEW(S)

JUN - 4

NDA 19-787 PFIZER NORVASC

CHEMIST'S REVIEW	1. ORGANIZATION HFD - 110	2. NDA Number 19-787
3. Name and Address of Applicant (City & State) Pfizer, Inc. 235 East 42nd Street New York, NY 10017-5755		4. Supplement(s) Number(s) S-018 Date(s) 04-14-99
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: (SUPAC CBE Supplement) an additional Stand Alone Packaging Site of Pfizer Inc. Parsippany, NJ for packaging of amlodipine besylate tablets.		
9. Pharmacological Category Antihypertensive and Antianginal	10. How Dispensed /x/ RX /__/ OTC	11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablet	13. Potency(ies) 2.5, 5, and 10 mg	
14. Chemical Name and Structure 3-Ethyl-5-methyl-2-(2-aminoethoxymethl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulfonic acid  		15. Records/Reports Current /x/ Yes /__/ No Reviewed /x/ Yes /__/ No
16. Comments:		
17. Conclusions and Recommendations: Satisfactory and recommended for approval.		
18. REVIEWER		
Name Ramsharan D. Mittal	Signature /S/	Date Completed 05/25/99
19. Distribution: /__/ Original Jacket /__/ Reviewer /__/ Division File /__/ CSO		

/S/
6-1-99

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APPLICATION NUMBER: NDA 19787/S018

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

April 14, 1999

Jean Lyons, MS
Director
Regulatory Affairs

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

NDA # 19-787 018
SCM

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 3 this submission). The purpose of this supplement is to add the Pfizer manufacturing facility located in Parsippany, New Jersey as a packaging site for the subject product.

Pursuant to the Guidance, the following information described in Overview, Section 2, 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 May 14, 1999. Ongoing stability data for amlodipine besylate tablets packaged at the Parsippany site will be submitted in subsequent annual reports.

ORIGINAL

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