CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S012

CORRESPONDENCE

Regulatory Affairs Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 2503 Fax 212 573 1563

Pfizer

NDA NO. 19-787 REF. NO. S-012
NDA SUPPL FOR SCS

Inna Kissen, PhD
Associate Director—Drug Regulatory Affairs

March 29, 1996

Raymond Lipicky, M.D., Director
Division of Cardio-Renal
Drug Products (HFD-110)
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852

RE: Norvasc (amlodipine besylate) Tablets
NDA #19-787
Supplemental application

Dear Dr. Lipicky;

We are submitting herein a supplemental application to our Norvasc (amlodipine besylate) tablets NDA #19-787.

The purpose of this supplement is to obtain approval for a change in the manufacturing process of amlodipine besylate. The currently approved process

The proposed process

The proposed change

The in-process control specifications and methods, and finished product specifications and methods remain the same.

ORIGINAL

Analytical data for amlodipine besylate drug substance made using manufactured according to the proposed process change, illustrates the quality to be the same as the drug substance manufactured according to the currently approved process. Analytical data for manufactured according to the proposed process change, illustrate the quality to be the same as for the manufactured according to the currently approved process. There is no change in the impurity profile of the finished drug substance as a result of this process change; and, the chemistry, synthetic route, and finished drug substance specifications are unchanged.

This supplement contains the currently approved process description for amlodipine besylate

the proposed specifications for

, the analytical testing results (Appendix IV), and the currently approved specifications for in-process control testing and amlodipine besylate drug substance (Appendix V). We are also including our stability commitment.

If you have any questions or comments, please contact the undersigned at (212) 573-2503.

Sincerely,

Inna Kissen, Ph.D.

IK:amw
Enclosure
NORVASC1.7

CONFIDENTIAL/TRADE SECRET INFORMATION
SUBJECT TO 18-USC-1905 AND TO WHICH ALL
CLAIMS OF PRIVILEGE AND CONFIDENTIALITY
ARE ASSERTED IN BOTH STATUTORY AND
COMMON LAW.

Regulatory Affairs Division
Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755
Tel 212 573 2503 Fax 212 573 1563

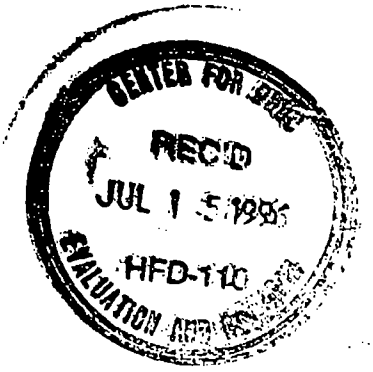
Pfizer

NEW CORRESP
B-002

July 11, 1996

Inna Kissen, PhD
Associate Director

Raymond Lipicky, M.D., Director
Division of Cardio-Renal
Drug Products (HFD-110)
Office of Drug Evaluation I
Center for Drug Evaluation and Research
Food and Drug Administration
1451 Rockville Pike
Rockville, MD 20852



Re: Norvasc (amlodipine besylate) tablets
NDA # 19-787

Dear Dr. Lipicky:

Pursuant to CFR 314.50 (d)(5) we are submitting additional information to our Norvasc (amlodipine besylate) Tablets, NDA #19-787.

Enclosed please find the final study report entitled "A single-blind parallel group study of the effects of single and multiple doses of amlodipine, lisinopril, diltiazem and simvastatin on the pharmacokinetics of alcohol in normal volunteers" (Protocol 053-016).

The above study showed that amlodipine alone or in combination with simvastatin and lisinopril had no statistically significant effect on the AUC_{0-8}, C_{max} or T_{max} of ethanol when compared to placebo.

Please add this information to the subject file.

If you have any questions or comments, please contact the undersigned at (212) 573-2503.

Sincerely

I. Kissen

Inna Kissen, Ph.D.
Enclosure
IK:amw
NORVASC1/8

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