CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S003

CORRESPONDENCE

ORIGINAL

Regulatory Affairs Division
Pfizer Inc
235 East 42nd Street
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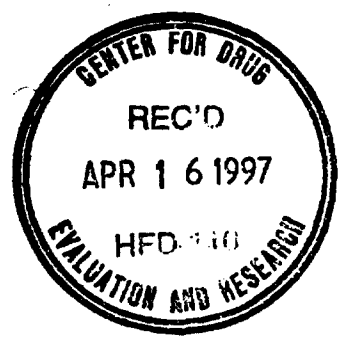
Inna Kissen, PhD
Associate Director—Drug Regulatory Affairs

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.

April 15, 1997

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

SUPPL NEW CORRESP
(SNC
5-003)



RE: Norvasc (amlodipine besylate) Tablets
IND
Information amendment - Clinical - Final Study Report
* Norvasc (amlodipine besylate) Tablets
NDA # 19-787

Dear Dr. Lipicky:

Pursuant to 21 CFR 312.31, enclosed is a final study report entitled "The Effect of Grapefruit Juice on the Pharmacokinetics of Amlodipine in Normal Volunteers" (protocol #053-017).

The study showed no pharmacokinetic, pharmacodynamic, or clinical effect of grapefruit juice on intravenous or oral administration of amlodipine in healthy male volunteers.

Please include this information in the subject file.

Sincerely,

I. Kissen

Inna Kissen, Ph.D.

* Cover letter only

Enclosure
IK:amw
NORV2.DOC/6

ORIGINAL

U.S. Pharmaceuticals Group
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235 East 42nd Street
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Assistant Director—Drug Regulatory Affairs

19-787 S-003
SCS

December 9, 1993

Raymond Lipicky, M.D., Director
Division of Cardio-Renal
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Office of Drug Evaluation I
Center for Drug Evaluation and Research
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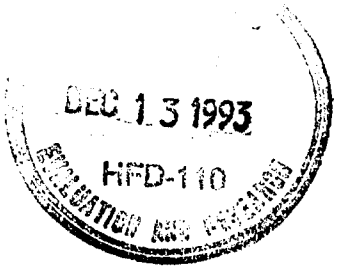
5600 Fishers Lane
Rockville, Maryland 20857



RE: Norvasc (amlodipine besylate) Tablets
NDA #19-787
Special Supplement

Dear Dr. Lipicky:

Pursuant to 21 CFR 314.70(c), we are submitting, in triplicate, a Special Supplement to our approved New Drug Application for Norvasc (amlodipine besylate), NDA #19-787.

Pfizer Pharmaceuticals, Inc. KM 58.2 Road #2, Barceloneta, Puerto Rico, is currently an approved manufacturing site for amlodipine besylate drug substance. The organic synthesis facilities at the Pfizer Barceloneta plant were recently expanded. In conformance with 21 CFR 314.70(c) (3), we are herein notifying you of the use of the expanded facility in Barceloneta, Puerto Rico, for the synthesis of amlodipine besylate, the drug substance used in the manufacture of Norvasc Tablets.

The expanded organic synthesis at Barceloneta is under the same production management as the currently approved facility. The responsibilities of the quality control unit, as defined in 21 CFR 211.22, are fulfilled by the same Quality Control Department as the currently approved facility. The materials of construction of the equipment in the expanded facility are in conformance with the equipment list provided in NDA #19-787. The manufacturing process in the new facility will not differ from the current process, covered by Process Monograph Description 05010a (copy attached).

The expanded facility was part of a recent inspection conducted by investigators from the San Juan, Puerto Rico District Office, from October 7 to October 15, 1991.

ORIGINAL

The implementation date for this change is January 1, 1994.

Please include this supplement in the file for Norvasc (amlodipine besylate) Tablets, NDA #19-787.

Sincerely,

I. Kissen

Inna Kissen

IK:amw
Enclosure
norvasc2

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.