

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19787/S005**

**CORRESPONDENCE**

U.S. Pharmaceuticals Group  
Pfizer Inc  
235 East 42nd Street  
New York, NY 10017-5755  
Tel 212 573 2503 Fax 212 573 1563



U.S. Pharmaceuticals

Inna Kissen, PhD  
Assistant Director—Drug Regulatory Affairs

October 25, 1994

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  
5600 Fishers Lane  
Rockville, Maryland 20857

NDA # 19-787 S-005  
SCM

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



Dear Dr. Lipicky:

Please refer to our approved application for Norvasc (amlodipine besylate) Tablets, NDA #19-787.

Pfizer herein requesting the approval of \_\_\_\_\_ as  
an additional alternate package site for Norvasc Tablets.

Enclosed is a DMF authorization letter from \_\_\_\_\_ referencing  
Norvasc Tablets.

A field copy of this supplement has been provided to Brooklyn District Office.

If you have any questions, please call my office.

Sincerely,

Inna Kissen, Ph.D.

IK:amw  
ENCLOSURE

ORIGINAL

norvasc2/8

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.