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**Application Number: NDA 19787/S016**

**APPROVAL LETTER**

MAR 9 1998

NDA 19-787/ S-016

Pfizer Pharmaceuticals  
Attention: Inna Kissen, Ph.D.  
235 East 42nd Street  
New York, NY 10017-5755

Dear Dr. Kissen:

Please refer to your January 20, 1998 supplemental new drug application (NDA) 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 user fee goal date is July 21, 1998.

The supplemental application provides for an alternate purification process using synthesis of the drug substance.

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,

*ISI 3/9/98*  
James H. Short, Ph.D.  
Acting Chemistry Team Leader, DNDC I  
Division of Cardio-Renal Drug Products  
Office of Drug Evaluation I  
Center for Drug Evaluation and Research