

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19787/S005**

**CHEMISTRY REVIEW(S)**

FEB - 7 1995

NDA 19-787

NORVASC

PFIZER

<b>CHEMIST'S REVIEW</b>		<b>1. ORGANIZATION</b> HFD - 110	<b>2. NDA Number</b> 19-787
<b>3. Name and Address of Applicant (City &amp; State)</b> Pfizer, Inc. 235 East 42nd Street New York, NY 10017-5755		<b>4. Supplement(s) Number(s)</b> S-005 (SCM) <b>Date(s)</b> 10-25-94	
<b>5. Drug Name</b> NORVASC	<b>6. Nonproprietary Name</b> Amlodipine Besylate		<b>8. Amendments &amp; Other (reports, etc) - Dates</b>
<b>7. Supplement Provides For:</b> Requesting the approval of _____ as an additional alternate package site for Norvasc Tablets.			
<b>9. Pharmacological Category</b> Antihypertensive and Antianginal	<b>10. How Dispensed</b> <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC		<b>11. Related IND(s)/ NDA(s)/DMF(s)</b>
<b>12. Dosage Form(s)</b> Tablet	<b>13. Potency(ies)</b> 2.5, 5, and 10 mg		
<b>14. Chemical Name and Structure</b> 3-Ethyl-5-methyl-2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulfonic acid			<b>15. Records/Reports Current</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>16. Comments:</b> The applicant requested for approval of _____ as an additional alternate package site for Norvasc Tablets. An authorization letter to refer to DMF _____ was provided. An EER request was submitted on 01/27/95. After receiving the reply from compliances, the applicant will be informed accordingly.			
<b>17. Conclusions and Recommendations:</b> An EER request was submitted on 1/27/95. Reply was received on 2/5/95 and as of 2/2/95 the status is acceptable. Approval letter is being sent to the applicant.			
<b>18. REVIEWER</b>			
<b>Name</b> Ramsharan D. Mittal	<b>Signature</b> <i>RSI</i>		<b>Date Completed</b> 02/07/95
<b>19. Distribution:</b> <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

*y* *RSI* - 217195