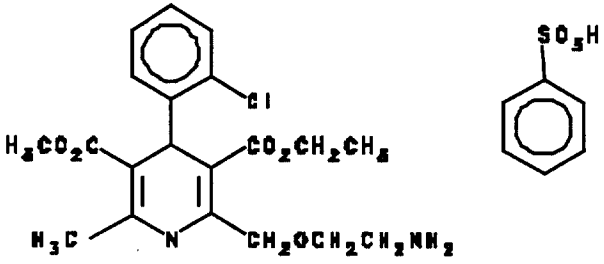



**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19787/S009**

**CHEMISTRY REVIEW(S)**

NOV | 1995

<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-009 <b>Date(s)</b> 08-14-95	
<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>  Labeling changes.			
<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>  Agency had received 10 reports of cholestatic hepatitis and 5 reports of elevated liver enzymes. As per Agency's request the applicant has revised the package insert labeling to reflect this information in the Adverse Reaction section. These changes do not effect the CMC related sections of the package insert.			
<b>17. Conclusions and Recommendations:</b>  None.			
<b>18. REVIEWER</b>			
<b>Name</b> Ramsharan D. Mittal		<b>Signature</b> 	<b>Date Completed</b> 10/30/95
<b>19. Distribution:</b> <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

