

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S019

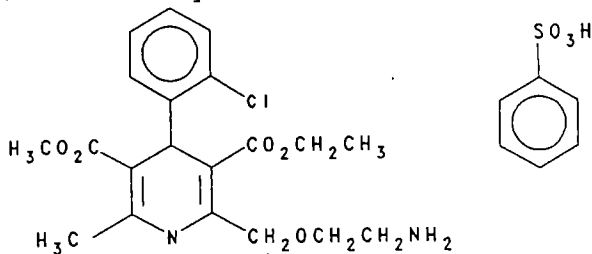
CHEMISTRY REVIEW(S)

NDA 19-787

PFIZER

NORVASC

359 - 7

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-787
3. Name and Address of Applicant (City & State) Pfizer, Inc. 235 East 42nd Street New York, NY 10017-5755		4. Supplement(s) Number(s) S-019 Date(s) 05-14-99	
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: (SUPAC CBE Supplement) an additional Stand Alone Packaging Site of for packaging of amlodipine besylate tablets.			
9. Pharmacological Category Antihypertensive and Antianginal	10. How Dispensed ☒ RX ☐ OTC		11. Related IND(s)/ NDA(s)/DMF(s)
12. Dosage Form(s) Tablet	13. Potency(ies) 2.5, 5, and 10 mg		
14. Chemical Name and Structure 3-Ethyl-5-methyl-2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulfonic acid			15. Records/Reports Current ☒ Yes ☐ No Reviewed ☒ Yes ☐ No
			
16. Comments:			
17. Conclusions and Recommendations: Satisfactory and recommended for approval.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>/S/</i>		Date Completed 05/25/99
19. Distribution: ☐ Original Jacket ☐ Reviewer ☐ Division File ☐ CSO			

/S/
8-12-99