

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S006

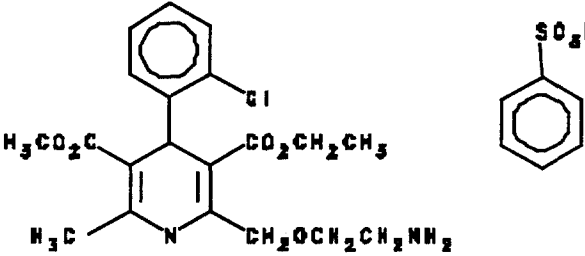
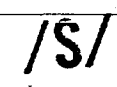
CHEMISTRY REVIEW(S)


JUN 19 1995

NDA 19-787

NORVASC

PFIZER

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) SCS-006 Date(s) 03-31-95	
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Replacement of particle size methodology for amlodipine besylate, the drug substance.			
9. Pharmacological Category Antihypertensive and Antianginal		10. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> 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 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16. Comments: The applicant requested for replacement of particle size methodology for amlodipine besylate, the drug substance for manufacturing of Norvasc Tablets. The present methodology uses The replacement methodology, uses			
17. Conclusions and Recommendations: The new methodology did not effect the specifications of drug substance, the changes are satisfactory and approval letter is being sent.			
18. REVIEWER -			
Name Ramsharan D. Mittal	Signature 		Date Completed 06/12/95
19. Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

 6/14/95