

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S015

CHEMISTRY REVIEW(S)

MAY 12 1997

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-015 Date(s) 02-28-97	
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: CHANGES BEING EFFECTED: Approval for Pfizer's new organic synthesis building at Groton Connecticut campus.			
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:			
17. Conclusions and Recommendations: Satisfactory and approval letter is being sent. An EER request was submitted on EES (Establishment Evaluation System) and as of 22-April, 1997, the supplement is acceptable.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>RS</i>		Date Completed 05/09/97
19. Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

RS 5/12/97