

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S011

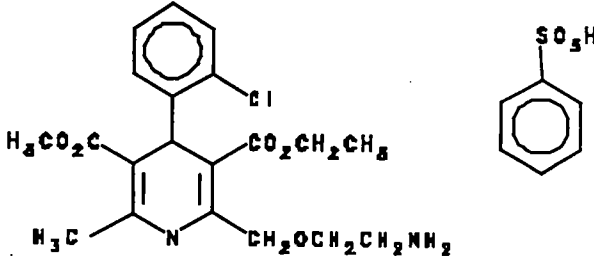
CHEMISTRY REVIEW(S)

NDA 19-447

PFIZER

NORVASC

FEB - 7 1996

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-011 Date(s) 01-22-96	
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Requesting the approval of a packaging site change for			
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 approval of a packaging site change for _____ is an approved contract packager for this NDA. The new site is located at _____ An authorization letter to refer to _____ DMF was provided. The applicant also submitted a stability commitment.			
17. Conclusions and Recommendations: An EER request for this facility _____ was submitted by Kathleen E. Jongedyk for NDA 19-614/S-017 on 07/31/95 and was approved on 01/22/96. A copy of the acceptable status is enclosed. Since, the status of this facility is acceptable and this supplement is recommended for approval. An approval letter is being sent to the applicant.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>/S/</i>		Date Completed 02/01/96
19. Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

/S/ 2/1/96