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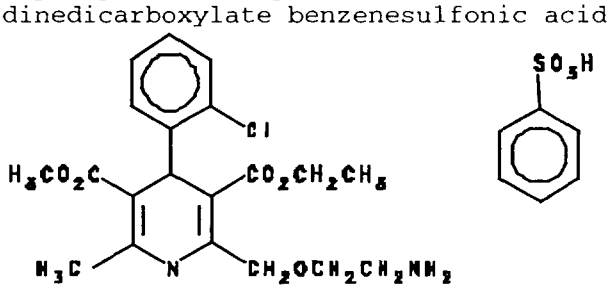
APPROVAL PACKAGE FOR:

APPLICATION NUMBER
19-787/S-007

Chemistry Review(s)

3211

JUN 12 1996

CHEMIST'S REVIEW	1. ORGANIZATION HFD - 110	2. NDA Number 19-787
3. Name and Address of Applicant (City & State) Pfizer, Inc. Eastern Point Road Groton, CT 06340		4. Supplement(s) Number(s) SES-007(AF) Date(s) 06-04-96
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: Final Printed Labeling.		
9. Pharmacological Category Antihypertensive and Antianginal	10. How Dispensed /x/ 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-aminoethoxymethl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulfonic acid 		15. Records/Reports Current /x/ Yes /___/ No Reviewed /x/ Yes /___/ No

16. **Comments:**

As per Agency's letter of April 22, 1996 the labelling supplement was approvable. In a meeting with the Division on May 28, 1996, an agreement was reached on final labeling. The applicant has provided copies of the final printed labeling.

17. **Conclusions and Recommendations:**

The labeling did not effect CMC related sections.

18. **REVIEWER**

Name	Signature	Date Completed
Ramsharan D. Mittal	/S/	06/12/96

19. **Distribution:**
/___/ Original Jacket /___/ Reviewer /___/ Division File /___/ CSO

/S/ 6/12/96

FEB - 2 1996

Environmental Assessment NDA 19-787 S-007

Amlodipine Besylate, NORVASC, oral

Pfizer Central Research
Groton, Connecticut 06340

Categorical exclusion from the requirement to prepare an Environmental Assessment applies to approval of this supplement because the drug product will not be administered at higher dosage levels, for longer duration or for different indications than were previously in effect . There is no data available to the FDA that establishes that, at the expected level of exposure, the drug product may be toxic to organisms in the environment. Reference: 21 CFR 25.24 (c)(2).

The supplement pertains to a labeling change, specifically the addition of safety information that supports the use of Norvasc as a safe and effective therapeutic option for the treatment of hypertension and/or angina in patients with congestive heart failure. Norvasc (tablet dosage form) NDA 19-787 was approved for the treatment of hypertension and angina on July 31, 1992 . Therefore, the supplement does not request approval for a different indication.

/S/ February 1, 1996

Florian Zielinski February 1, 96
Review Chemist, ONDC I

Distribution

/S/ 2/2/96

Original: NDA 19-787 S-007
cc: HFD 110 Division file
HFD 110 FW Zielinski
HFD 110 CSO, Dave Roeder
HFD 357 Nancy Sager