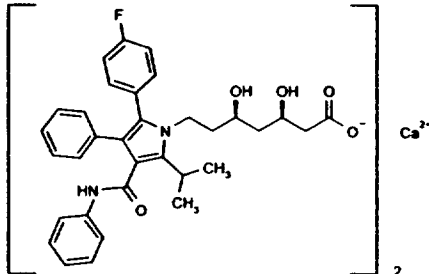


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-702/S025

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. Organization CDE/HFD-510 Division Of Metabolism And Endocrine Drug Products		2. NDA # 20-702 Approved: 17-Dec-1996	
3. Name and Address of Applicant Parke-Davis Pharmaceutical Research Division of Warner-Lambert Company 2800 Plymouth Road P.O. Box 1047 Ann Arbor, MI 48106-1047 (313) 966-5000		4. Supplement SE8-025 Doc. 10-AUG-2000 Rec. 11-AUG-2000	
		5. Name of the Drug Lipitor Tablets	
		6. Nonproprietary Name Atorvastatin Calcium	
7. Supplement provides for changes in the Geriatric Use _____ _____ of the labeling.		8. Amendment Doc. 10-AUG-2000 Rec. 11-AUG-2000	
9. Pharmacological Category Lipid Modifier. HMG-CoA reductase inhibitor/ Antihyperlipoproteinemic agent.		10. How Dispensed Rx	11. Related -N. A.-
12. Dosage Form Tablet		13. Potency 10-, 20-, 40- and 80-mg	
14. Chemical Name and Structure			
<p>Atorvastatin Calcium (C₃₃H₃₄FN₂O₅)₂Ca FW = 2 x 557.7 + 40.0 = 1155.38 (anhydrous calcium salt) CAS 134523-03-8 CAS 134523-00-5 (atorvastatin) FW free acid C₃₃H₃₄FN₂O₅ = 558.66 FW calcium salt trihydrate (C₃₃H₃₄FN₂O₅)₂Ca·3H₂O = 1209.42</p>			
<p>[R-(R*,R*)]-2-(4-fluorophenyl)-β, -dihydroxy-5-(1-methylethyl)-3-phenyl-4-[(phenylamino)carbonyl]-1H-pyrrole-1-heptanoic acid calcium salt (2:1)</p>			
15. Comments: This supplement (Parke-Davis ref. # 114), SE8-025, provides for changes in the Geriatric Use _____ of the labeling. The applicant, Parke-Davis, also has submitted an updated Environmental Assessments (EA) as part the supplement because production of the active ingredient, atorvastatin calcium, has exceeded the quantities originally projected for 5 years, thereby exceeding the 1 ppb threshold exemption. Revised Confidential and Freedom of Information Environmental Assessments have provided. The EA section was send for consult to Nancy Segar (HFD-357) on 05-SEP-2000. After review, a finding of no significance impact (FONSI) was recommended by Melissa Maust (HFD-357) on 25-OCT-2000. The provided CMC information meets the regulatory requirements.			
16. Conclusions and Recommendations: There are no changes regarding Chemistry and Manufacturing Controls. The updated Environmental Assessment information fulfils the regulatory requirements. Issue Approval Letter.			
17. Reviewer Name (and Signature)		Date Completed 31-OCT-2000	
Xavier Ysem, PhD			
R/D INITIATED BY		filename: /nda/20702s25.doc	
DISTRIBUTION: Original: NDA 20-702 cc: HFD-510 Division File / MooreS/ SimoneauM/ YsemX			

AP

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/s/

Xavier Ysern
4/16/01 09:39:17 AM
CHEMIST

efficacy supplement geriatric use no CMC changes

Stephen Moore
4/17/01 03:03:53 PM
CHEMIST

**APPEARS THIS WAY
ON ORIGINAL**