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APPLICATION NUMBER: 019643/S055

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. ORGANIZATION CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		2. NDA # 19-643 Original NDA approved: 13-AUG-1987	
3. NAME AND ADDRESS OF APPLICANT Merck & Co., Inc. P.O. Box 4 West Point, PA 19486 Phone (610) 397-2516		4. SUPPLEMENT SE1-055 Doc. 28-APR-98 Rec. 29-APR-98	
		5. Name of the Drug Mevacor	
		6. Nonproprietary Name Lovastatin	
7. SUPPLEMENT PROVIDES for a new indication for the primary prevention of coronary heart disease.		8. AMENDMENT --	
9. PHARMACOLOGICAL CATEGORY HMG-CoA reductase inhibitor	10. HOW DISPENSED Oral	11. RELATED -N. A. -	
12. DOSAGE FORM Tablet	13. POTENCY 10, 20, and 40 mg		
14. CHEMICAL NAME AND STRUCTURE Lovastatin $C_{24}H_{36}O_5$ F.W. = 404.55 CAS 56180-94-0 <i>[1S-[1α(R*), 3α, 7β, 8β (2S*, 4S*), 8α]]-1,2,3,7,8,8a-hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)ethyl]-1-naphthalenyl 2-methylbutanoate.</i> For Structure, see the original chemistry review.			
15. COMMENTS Regarding CMC information for this Efficacy Supplement: There are no proposed changes to existing CMC information nor CMC portions of the existing labeling. Merck is requesting a categorical exclusion from the requirements to prepare an Environmental Assessment under 21 CFR §25.31(b). The production of MEVACOR Tablets meets the requirements of a categorical exclusion because the estimated concentration of drug substance lovastatin at the point of entry, referred to as the Expected Introduction Concentration (EIC), into the aquatic environment will be [REDACTED]. To the best of the firm's knowledge no extraordinary circumstances exist in regard to this action.			
16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided. From the CMC point of view, this supplement may be approved.			
17. REVIEWER NAME (AND SIGNATURE) Sharon Kelly, Ph.D. /S/ [REDACTED]		DATE COMPLETED 08-FEB-1999	
R/D INITIALED BY [REDACTED]		filename: 19643snda.doc	
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