

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 19-766/S040**

**CHEMISTRY REVIEW(S)**

**CHEMIST'S REVIEW**

<b>1. ORGANIZATION</b> CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		<b>2. NDA #</b> 19-766 Original NDA approved: 23-DEC-1991	
<b>3. NAME AND ADDRESS OF APPLICANT</b> Merck & Co., Inc. P.O. Box 4 West Point PA 19486 (Phone): 610-397-2944		<b>4. SUPPLEMENT</b> SE2-040 30-JUN-99 (Rec'd 07-Jul-99)	
		<b>5. Name of the Drug</b> ZOCOR™	
		<b>6. Nonproprietary Name</b> Simvastatin	
<b>7. SUPPLEMENT PROVIDES</b> data to support revisions to the dosage and administration section of the label, i.e., to provide the option of a starting dose of 40mg.		<b>8. AMENDMENT</b> --	
<b>9. PHARMACOLOGICAL CATEGORY</b> HMG-CoA inhibitor used to treat hyperlipidemia	<b>10. HOW DISPENSED</b> Oral	<b>11. RELATED</b> -N. A. -	
<b>12. DOSAGE FORM</b> Tablet	<b>13. POTENCY</b> 5, 10, 20, 40 & 80 mg		
<b>14. CHEMICAL NAME AND STRUCTURE</b> Butanoic acid, 2,2-dimethyl-, 1,2,3,7,8,8 $\alpha$ -hexahydro-3,7-dimethyl-8-[2-(tetrahydro-4-hydroxy-6-oxo-2H-pyran-2-yl)-ethyl]-1-naphthalenyl ester, [1S-[1 $\alpha$ ,3 $\alpha$ ,7 $\beta$ ,8 $\beta$ (2S*,4S*),-8 $\alpha$ $\beta$ ]]; C <sub>25</sub> H <sub>38</sub> O <sub>5</sub> , F.W. = 418.57, CAS 56180-94-0 (For the structure, see Chemistry Review #1, dated 16-MAR-1988 in Vol. 3.1 of NDA 19-766).			
<b>15. COMMENTS</b> See attached			
<b>16. CONCLUSIONS AND RECOMMENDATIONS</b> A request for a categorical exclusion from the requirements to prepare an Environmental Assessment is provided. From a Chemistry point of view, this supplement can be approved. Issue approval letter.			
<b>17. REVIEWER NAME (AND SIGNATURE)</b> COMPLETED 13-APR-2000 <i>April 13, 2000</i> Sharon Kelly, PhD R/D INITIATED BY <span style="border: 1px solid black; padding: 2px 10px;">/S/</span>		<b>DATE</b>	
filename: 19766NDASup			
DISTRIBUTION: Original: sNDA 19-766 cc: HFD-510 Division File CSO Reviewer			

AP

*15* /S/  
*4/13/2000*