

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 19-898/S032

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

1. ORGANIZATION CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		2. NDA # 19-898 Original NDA approved: 31-OCT-1991	
3. NAME AND ADDRESS OF APPLICANT Bristol-Myers Squibb P.O. Box 4000 Princeton, NJ 08543 (Phone): 609-252-4000		4. SUPPLEMENT SE1-032 13-APR-1999 (Rec. 13-APR-1999)	
		5. Name of the Drug PRAVACHOL™	
		6. Nonproprietary Name Pravastatin sodium	
7. SUPPLEMENT PROVIDES Efficacy Supplement for secondary prevention of cardiovascular events.		8. AMENDMENT --	
9. PHARMACOLOGICAL CATEGORY Lipid-lowering agent	10. HOW DISPENSED Oral	11. RELATED -N. A. -	
12. DOSAGE FORM Tablet	13. POTENCY 10mg, 20mg and 40mg		
14. CHEMICAL NAME AND STRUCTURE [1S-[1α(βS*, φS*)2α,6α,8β(R*),8α]]-1,2,6,7,8α-hexahydro-β,φ,6-trihydroxy-2-methyl-1-oxobutoxy)-1-nephtaleneheptanoic acid, monosodium salt			
15. COMMENTS See next page.			
16. CONCLUSIONS AND RECOMMENDATIONS Satisfactory CMC information has been provided to support the request for waiver of environmental assessment. From the Chemistry point of view, this supplement can be approved.			
17. REVIEWER NAME (AND SIGNATURE) COMPLETED 14-JUL-1999 Sharon Kelly, PhD R/D INITIATED BY		DATE July 14, 1999	
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