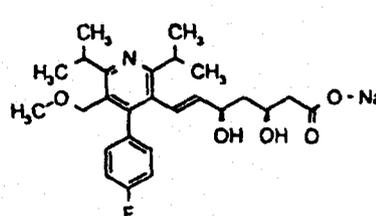


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 020740/S002

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW

Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products		NDA # 20-740 Approved: 26-AUG-1997	
Name and Address of Applicant: Bayer Corporation Pharmaceutical Division 400 Morgan Lane West Haven, CT 06516-4175 Phone (203) 812-2000 812-5145		Supplement SE2-002 Doc. 16-JUL-1998 Rec. 17-JUL-1998	
		Name Of The Drug BAYCOL Tablets	
		Nonproprietary Name Cerivastatin Sodium Tablets	
Supplement provides for an additional strength, 0.4-mg, of Baycol (cerivastatin sodium) tablets.		Amendment(s) Doc. 13-AUG-1998 Rec. 14-AUG-1998	
Pharmacological Category HMG-CoA reductase Inhibitor. Hypercholesterolemia.	How Dispensed Oral Rx	Supporting Documents --	
Dosage Form Tablets	Potencies 0.05-, 0.1-, 0.2-, 3.0- and 4.0-mg -		
Chemical Name and Structure			
<p>Cerivastatin sodium</p> <p>$C_{26}H_{33}FNO_3Na$</p> <p>MW = 481.5</p> <p>CAS 143201-11-0</p> <p>(+)-[3R,5S,(E)]-Sodium-7-[4-(4-fluorophenyl)-2,6-diisopropyl-5-methoxymethyl-pyrid-3-yl]-3,5-dihydroxy-6-heptenoate</p>			
			
<p>Comments: The July 16, 1998, efficacy supplement requests the approval of an additional tablet strength, 0.4-mg Baycol (cerivastatin sodium) tablets. Manufacture and in-process controls, specifications and tests, and packaging configurations, are all similar to the approved for the lower strengths 0.05-, 0.1-, 0.2- and 0.3-mg tablets. By-product/Degradation profiles of the new strength are similar to those of the approved strengths. Manufacturing facilities have found acceptable (based on profiles) by the district office. The Office of Clinical Pharmacology and Biopharmaceutics (Dr. Hae-Young Ahn, Division of Pharmaceutical Evaluation II) will review Bioequivalence of the proposed 0.4-mg strength to the lower approved strengths.</p>			
<p>Conclusions and Recommendation Satisfactory CMC information has been provided to support the use and commercialization of the 0.4-mg strength tablets. From the chemistry point of view, this supplement can be approved. Dissolution and Bioequivalence issues or concerns, if any, will be given by the Office of Clinical Pharmacology and Biopharmaceutics (see Dr. Hae-Young Ahn, Division of Pharmaceutical Evaluation II, review).</p>			
Date Completed: 20-APR-1999		/S/ [Redacted]	
R/D Init.		Xavier Ysern, PhD	
filename: /nda/20740s02.doc			
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AP

/S/ [Redacted]

4/26/99