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APPLICATION NUMBER: 20-740/S008/S013

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 SE2-008 Doc. 22-SEP-1999 Rec. 23-SEP-1999
	Name Of The Drug BAYCOL Tablets
	Nonproprietary Name Cerivastatin Sodium Tablets
Supplement provides for an additional strength, 0.8-mg, of Baycol (cerivastatin sodium) tablets.	Amendment(s) -

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-, 4.0- and 8.0-mg	

Chemical Name and Structure

Cerivastatin sodium

$C_{26}H_{33}FNO_5Na$

MW = 481.5

CAS 143201-11-0

(+)-[3R,5S,(E)]-Sodium-7-[4-(4-fluorophenyl)-2,6-diisopropyl-5-methoxymethyl-pyrid-3-yl]-3,5-dihydroxy-6-heptenoate

Comments: This efficacy supplement, SE2-008, dated September 23, 1999, requests the approval of an additional tablet strength, 0.8-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-, 0.3 and 0.4-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 0.8-mg strength to the lower approved strengths. A form 483 was issued after inspection to one of the facilities involved in the manufacture of drug product. After correction of the deficiencies stated in the Form 483, the Office of Compliance on July 19, 2000 issued an acceptable recommendation.

Conclusions and Recommendation Satisfactory CMC information has been provided to support the use and commercialization of the 0.8-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. Jim Wei, Division of Pharmaceutical Evaluation II, review).

Date Completed: 19-JUL-2000

/S/
Xavier Ysem, PhD

R/D Init.

filename: _____

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7/19/00