

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-740/S016

Trade Name: Baycol Tablets

Generic Name: cervistatin sodium

Sponsor: Bayer Pharmaceutical Division

Approval Date: January 23, 2001

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APPLICATION NUMBER:
NDA 20-740/S016

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APPROVAL LETTER



NDA 20-740/S-016

Bayer Pharmaceutical Division
Attention: Frederich Sundermann
Associate Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Mr. Sundermann:

Please refer to your supplemental new drug application dated November 20, 2000, received November 21, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol (cerivastatin sodium) Tablets.

This supplemental new drug application provides for the extension of the expiration date of Baycol (cerivastatin) 0.4 mg tablets from 24 months to 36 months.

We have completed the review of this supplemental application, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Margaret Simoneau, R.Ph., Regulatory Project Manager, at (301) 827-6418.

Sincerely,

{See appended electronic signature page}

Stephen K. Moore, Ph.D.
Chemistry Team Leader I for
Division of Metabolic and

Endocrine Drug Products, (HFD-510)
DNDC II, Office of New Drug Chemistry
Center for Drug Evaluation and Research

/s/

Stephen Moore

1/23/01 01:38:14 PM

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APPLICATION NUMBER:
NDA 20-740/S016

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 SCE-016 Doc. 20-NOV-2000 Rec. 21-NOV-2000 Name Of The Drug BAYCOL Tablets Nonproprietary Name Cerivastatin Sodium Tablets
Supplement provides for the extension of the expiration date of Baycol (cerivastatin) 0.4-mg tablets from 24 months to 36 months.		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- and 4.0-mg	
Chemical Name and Structure		
Cerivastatin sodium C ₂₆ H ₃₃ FNO ₅ N MW = 481.5 CAS 143201-11-0		
(+)-[3 <i>R</i> ,5 <i>S</i> ,(<i>E</i>)]-Sodium-7-[4-(4-fluorophenyl)-2,6-diisopropyl-5-methoxymethyl-pyrid-3-yl]-3,5-dihydroxy-6-heptenoate		
<p>Comments: Supplement SCE-016, dated November 16, 2000, requests the extension of the expiration date of Baycol (cerivastatin) 0.4-mg tablets from 24 months to 36 months. In support of this request, the applicant provides stability data for samples from production scale batches of Baycol 0.4-mg tablets stored up to weeks at accelerated storage conditions (RH) and weeks (months) at room temperature (25°C/60% RH). The batches were packaged in HDPE bottles of 30 an. tablets, and There is a slight increase in the total amounts of both, unknowns and in by and degradation products, in accelerated conditions. In all the cases the results meet specifications. The maximum recorded sum of unknowns is In the case of all by and degradation products, the maximum recorded sum is which is below the specification of Water content specification is As expected, water content increases slightly upon storage in humidity. The percentage of water for samples packaged in are greater than for those packaged in HDPE bottles The extension of the expiration date for Baycol 0.2- and 0.3-mg Tablets from 24 months to 36 months was approved on August 23, 1999 (SCE-005 19-JUL-1999). Now all three strengths, 0.2-, 0.3- and 0.4-mg, have the same shelf life of three years in all package configurations when stored below 25°C (77°F).</p>		
<p>Conclusions and Recommendation: Satisfactory CMC information has been provided to support the extension of the expiration date for Baycol 0.4-mg Tablets from 24 to 36 months. From the chemistry point of view, this supplement can be approved. Issue approval letter.</p>		
Reviewer Name (and signature) Xavier Ysern, PhD		Date Completed: 11-DEC-2000
R/D Init.		filename: /nda/20740s16.doc
DISTRIBUTION: Original: NDA 20-740 cc: HFD-510 Division File/ PSimoneau/ SMoore/ XYsern		

AP

/s/

Xavier Ysern
12/11/00 04:46:17 PM
CHEMIST

AP

Stephen Moore
12/12/00 05:23:59 PM
CHEMIST