CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-740/S-010

Trade Name: Baycol

Generic Name: (cerivastatin sodium)

Sponsor: Bayer Corporation Pharmaceutical Division

Approval Date: December 22, 1999

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-010

CONTENTS

Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
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Medical Review(s)	
Chemistry Review(s)	X
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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

20-740/S-010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-740/S-010

Bayer Corporation Pharmaceutical Division
Attention: William E. Maguire
Director Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516

DEC 22 1999

Dear Mr. Maguire:

Please refer to your supplemental new drug application dated September 30, 1999, received October 1, 1999, 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 a change

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, contact Margaret Simoneau, R.Ph., Regulatory Management Officer, at (301) 827-6418.

Sincerely,

for S Moore 12-22-99

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

cc:
Archival NDA 20-740
HFD-510/Div. Files
HFD-510/M. Simoneau
HFD-510/XYsern/SMoore
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/December 6, 1999
Initialed by:XYsern12.13.99/SMoore12.14.99/EGalliers12.20.99
final:Mas12.22.99
filename: 20740.10

APPROVAL (AP)

FOI: Please redact the phrase

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-010

CHEMISTRY REVIEW(S)

NOV 18 1999

CHEMIST'S REVIEW

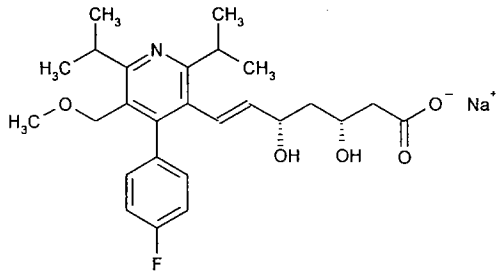
Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**NDA # 20-740** Approved: 26-AUG-1997
Name and Address of Applicant: Bayer Corporation Pharmaceutical Division 400 Morgan Lane West Haven, CT 06516-4175 Phone (203) 812-2000 812-5145	**Supplement** SCS-010 Doc. 30-SEP-1999 Rec. 01-SEP-1999 **Name Of The Drug** BAYCOL Tablets **Nonproprietary Name** Cerivastatin Sodium Tablets
Supplement provides for a change.	**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**	

Chemical Name and Structure

Cerivastatin sodium

C26H33FNO5N
MW = 481.5
CAS 143201-11-0



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

Comments: This supplement provides for

Conclusions and Recommendation: Satisfactory CMC information has been provided to support

and does not impact in the quality of the drug product. From the chemistry point of view, this supplement can be approved.

Date Completed: 10-NOV-1999

Xavier Ysern, PhD

R/D Init.

filename: /nda/20740s10.doc

DISTRIBUTION: Original: NDA 20-740 cc: HFD-510 Division File/ PSimoneau/ SMoore/ XYsern

AP

11/18/99

3 Page(s) Withheld

✓ § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-740 SOLO

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APPLICATION NUMBER:

20-740/S-010

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT - 6 1999

NDA 20-740/S-010

Bayer Corporation Pharmaceutical Division
400 Morgan Lane
West Haven, CT 06516

Attention: William E Maguire
Director, Regulatory Affairs

Dear Mr. Maguire:

We acknowledge receipt of your supplemental application for the following:

Name of Drug:	Baycol® (cerivastatin sodium) Tablets
NDA Number:	20-740
Supplement Number:	S-010
Date of Supplement:	September 30, 1999
Date of Receipt:	October 01, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on November 30, 1999, in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Office of Drug Evaluation II
Attention: Document Control Room 14B-19
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Enid Galliers
Chief, Project Management Staff
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Original NDA 20-740/S-010
HFD-510/Div. Files
HFD-510/CSO/M. Simoneau

filename: C:\WPFILES\20740.ACK

SUPPLEMENT ACKNOWLEDGEMENT

ORIGINAL

Bayer

Pharmaceutical Division

NDA NO. 20-740 REF NO. 010

NDA SUPPL FOR SCS

Bayer Corporation
400 Morgan Lane
West Haven, CT 06516-4175
Phone: 203 812-2000

September 30, 1999

Solomon Sobel, MD, Director
Division of Metabolism and Endocrine Drug Products
Office of Drug Evaluation II HFD-510
Center for Drug Evaluation and Research
Food and Drug Administration
ATTN: Document Control Room 14B-04
5600 Fishers Lane
Rockville, MD 20857

CENTER FOR DRUG EVALUATION AND RESEARCH
REC'D
OCT - 1 1999
HFD-510

Re: NDA 20-740
BAYCOL® (cerivastatin sodium tablets)
Supplement – Chemistry, Manufacturing and Controls

Dear Dr. Sobel,

The Bayer Corporation Pharmaceutical Division is submitting this supplement per 21 CFR 314.70 (b) to NDA 20-740, BAYCOL® (cerivastatin sodium tablets). The purpose of this supplement is to revise the assay specifications for BAYCOL® (cerivastatin sodium tablets).

An explanation and support for this request are provided in the attached documents.

If there are any questions regarding this submission please contact me at (203) 812-2435.

Sincerely,

for

William E. Maguire
Director, Regulatory Affairs

/fks

REVIEWS COMPLETED
AP LTR 12-22-99
CSO ACTION:
☑ LETTER ☐ NA ☐ APMO
12-22-99
CSO INITIALS DATE

cc: J. Marzilli – FDA Stoneham, MA – Desk Copy
A. Warchut – FDA Hartford - Desk Copy
X. Ysern – FDA Reviewing Chemist