CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-740/S-012

Trade Name: Baycol

Generic Name: (cerivastatin sodium)

Sponsor: Bayer Corporation Pharmaceutical Division

Approval Date: July 3, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-012

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	**X**
Approvable Letter	
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Medical Review(s)	
Chemistry Review(s)	**X**
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	**X**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-012

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL - 3 2000

NDA 20-740/S-012

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

Dear Mr. Maguire:

Please refer to your supplemental new drug application dated June 1, 2000, received June 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol (cerivastatin sodium).

We acknowledge receipt of your submission dated June 16, 2000.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of

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,

Stephen K. Moore 6/30/2000

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/MAS
HFD-510/XYsern/SMoore
HFD-095/DDMS-IMT
HFD-820/DNDC Division Director
DISTRICT OFFICE

Drafted by: Mas/June 29, 2000
Initialed by:XYsern6.29.00/SMoore6.29.00/EGalliers6.29.00
final:Mas6.30.00
filename: 20740.12

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-012

CHEMISTRY REVIEW(S)

JUN 19 2000

CHEMIST'S REVIEW

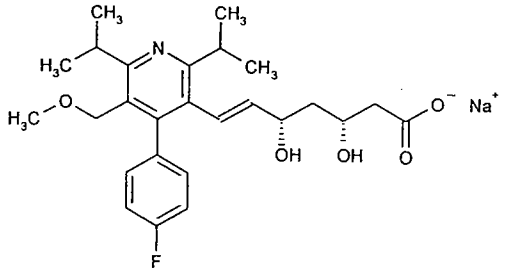
Organization CDER/HFD-510 Division of Metabolism and Endocrine Drug Products	**NDA # 20-740** Approved: 26-AUG-1997
Name and Address of Applicant: Bayer Corporation Pharmaceutical Division 400 Morgan Lane West Haven, CT 06516-4175 Phone (203) 812-2000 812-5145	**Supplement** SCM-012 Doc. 01-JUN-2000 Rec. 02-JUN-2000 **Name Of The Drug** BAYCOL Tablets **Nonproprietary Name** Cerivastatin Sodium Tablets
Supplement provides for the addition of.	**Amendment(s)** --

Pharmacological Category HMG-CoA reductase Inhibitor. Hypercholesterolemia.	**How Dispensed** Oral Rx	**Supporting Documents** --
Dosage Form Tablets	**Potencies**	

Chemical Name and Structure

Cerivastatin sodium

$C_{26}H_{33}FNO_5N$
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:

acceptable by the Office of Compliance based District Recommendation dated June 15, 2000 (EER Summary attached).

Conclusions and Recommendation: Satisfactory CMC information has been provided to support . From the chemistry point of view, this approved. **Issue approval letter.**

Reviewer Name (and signature) Xavier Ysern, PhD Ysern **Date Completed:** 16-JUN-2000

R/D Init.

filename: /nda/20740s12.doc

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

AP

Stephen Moore 6/19/2000

2 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 21-740 5012

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 20740/012**
Stamp: **02-JUN-2000** Regulatory Due: **02-DEC-2000**
Applicant: **BAYER**
400 MORGAN LANE
WEST HAVEN, CT 065164175

Priority: **1S** Org Code: **510**
Action Goal: District Goal: **28-OCT-2000**
Brand Name: **BAYCOL (CERIVASTATIN)TABS**
Established Name:
Generic Name: **CERIVASTATIN**
Dosage Form: **TAB (TABLET)**
Strength:

FDA Contacts: **X. YSERN (HFD-510) 301-827-6420 , Review Chemist**

Overall Recommendation:

ACCEPTABLE on 15-JUN-2000 by M. EGAS (HFD-322) 301-594-0095

Establishment: **9610496**
BAYER AG

WUPPERTAL, , GM

DMF No:
AADA No:

Profile: **TCM** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date: **15-JUN-2000**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**

Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-740/S-012

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

Bayer

Pharmaceutical
Division

REGULATORY AFFAIRS

FACSIMILIE MESSAGE

Date: 16-Jun-00	# Pages (incl. this pg): 7
To: Dr. X. YSERN	From: FRED SUNDERMANN
Company: FDA	Division: Pharmaceutical
Fax: 301-443-9282	Fax: 203-812-5029
Phone: 301-827-6378	Phone: 203-812-2681

RE: NDA 20-740; S-012

Dr. Ysern – Attached is the document you requestd.

Fred Sundermann
Regulatory Affairs

6 Page(s) Withheld

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

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Administrative- 20-740
S012

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-740/S-012

Bayer Corporation Pharmaceutical
400 Morgan Lane
West Haven, CT 06516

JUN - 7 2000

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-012

Date of Supplement: June 1, 2000

Date of Receipt: June 2, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on August 1, 2000, 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-012
HFD-510/Div. Files
HFD-510/CSO/Simoneau

filename:

SUPPLEMENT ACKNOWLEDGEMENT

ORIGINAL

Bayer

NDA NO. 20746 SEQ NO. 012
NDA SUPPL FOR SCM

Pharmaceutical Division

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

June 1, 2000

John Jenkins, M.D., Acting 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

Re: NDA 20-740
BAYCOL® (cerivastatin sodium tablets)
Special Supplement – Changes Being Effected

Dear Dr. Jenkins,

The Bayer Corporation is submitting this supplement per 21 CFR 314.70 (c) to NDA 20-740, BAYCOL® (cerivastatin sodium tablets). BAY w 8877 used to produce BAYCOL® tablets

The changes are explained in detail in on the attached documents. This change will be implemented 30 days from the date of this submission.

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

Sincerely,

William E. Maguire
Director, Regulatory Affairs

REVIEWS COMPLETED
CSO ACTION:
☐ LETTER ☐ N.A.L. ☐ MEMO
CSO INITIALS DATE

/fks
cc: G. Costello – FDA Stoneham, MA
X. Ysern – FDA Reviewing Chemist