CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 020740

Trade Name: BAYCOL 0.05 MG, 0.1 MG, 0.2 MG, 0.3 MG

Generic Name: CERVISTATIN SODIUM TABLETS

Sponsor: BAYER CORPORATION PHARMACEUTICAL DIVISION

Approval Date: 06/26/97

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Medical Review(s)	X			
Chemistry Review(s)	X			
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Pharmacology Review(s)	X			
Statistical Review(s)	X			
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)	X			
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APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-740

JUN 26 1997

Bayer Corporation, Pharmaceutical Division
Attention: Nancy Motola, Ph.D.
Deputy Director, Regulatory Affairs
400 Morgan Lane
West Haven, CT 06516-4175

Dear Dr. Motola:

Please refer to your new drug application dated June 26, 1996, received June 26, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol™ (cerivastatin sodium tablets), 0.05 mg, 0.1 mg, 0.2 mg, and 0.3 mg.

We acknowledge receipt of your submissions dated July 2, August 15, September 20(2), October 4 and 25, and December 27, 1996, and January 8, 14, and 28, February 7 and 10(2), March 6 and 7(2), April 11(2), 22, 23, and 24, May 16, 21, 22, 27, 28(2), 29(2), and 30, and June 2(2), 4, 5, 24(2), 25(2), and 26, 1997.

The User Fee goal date for this application is June 26, 1997.

This new drug application provides for use of Baycol™ as an adjunct to diet for the reduction of elevated total and LDL cholesterol levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb) when the response to dietary restriction of saturated fat and cholesterol and other non-pharmacological measures alone has been inadequate.

We have completed the review of this application as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft physician labeling dated June 26, 1997, and the draft carton and container labeling dated June 26, 1996, as amended June 5, 1997, including the 0.05 mg and 0.1 mg tablets (bottles of 100) which are not listed in the draft labeling. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the referenced draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-740. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Metabolic and Endocrine Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

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, please contact Margaret Simoneau, R.Ph., Project Manager, at 301-443-3510.

Sincerely yours,

James Bilstad, M.D.
Director
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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FINAL PRINTED LABELING

FINAL PRINTED LABELING HAS NOT BEEN SUBMITTED TO THE FDA.

DRAFT LABELING IS NO LONGER BEING SUPPLIED SO AS TO ENSURE ONLY CORRECT AND CURRENT INFORMATION IS DISSEMINATED TO THE PUBLIC.