CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-740/S008/S013

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-740/S-008 and S-013

JUL 21 2000

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

Dear Mr. Maguire:

Please refer to your supplemental new drug applications dated September 22, 1999, received September 23, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Baycol (cerivastatin sodium tablets).

We acknowledge receipt of your submissions dated September 23, 1999, and January 20, June 9, 12, 15, 19, and 27, and July 7, 13, and 20, 2000.

Supplemental - 008 provides for the use of Baycol (cerivastatin sodium tablets) for the reduction of elevated LDL-cholesterol in a new, higher strength tablet, 0.8 mg, and for extension of the dosage range to 0.8 mg daily.

Supplement - 013 provides for the additional indication of increasing HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Frederickson Types IIa and IIb). The **INDICATIONS AND USAGE** section of the package insert for Baycol will state "Baycol (cerivastatin sodium tablets) is indicated as an adjunct to diet to reduce elevated Total-C, LDL-C, Apo B, and TG and to increase HDL-C levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson Types IIa and IIb). . . ." In addition, this change is reflected in the **CLINICAL PHARMACOLOGY** section of the package insert by inclusion of summary data on the HDL-C changes observed in the pooled Baycol placebo-controlled studies.

We have completed the review of these supplemental applications, 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 agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 20, 2000, and immediate container labels submitted September 22, 1999).

Please submit 20 paper 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. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999).

For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-740/S-008 and S-013." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that a Written Request (WR) for pediatric studies in patients with heterozygous familial hypercholesterolemia (heFH) was sent to you on February 2, 2000. No specific studies in Frederickson Types IIa and IIb are required. We hereby waive the requirement for pediatric studies in these groups, and we defer submission of pediatric studies in heFH until November 30, 2002.

In addition, please submit three copies of the introductory promotional materials 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 this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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.

APPEARS THIS WAY
ON ORIGINAL

If you have any questions, call William C. Koch, R.Ph., Regulatory Project Manager, at (301) 827-6412.

Sincerely,

/S/

John K. Jenkins, M.D.
Acting Director
Division of Metabolic
and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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