CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 19-898/S032

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-898/S-032

FEB 10 2000

Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Fred Henry
Director, Global Regulatory Strategy
P.O. Box 4000
Princeton, NJ 08543

Dear Mr. Henry:

Please refer to your supplemental new drug application dated April 13, 1999, received April 13, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pravachol (pravastatin) Tablets.

We acknowledge receipt of your submissions dated June 22, July 29, August 26, September 21, October 12, and December 17, 1999, and January 21 and February 4 and 8, 2000.

This supplemental new drug application provides for a new indication, based on the results of the Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) study, for the use of pravastatin in patients with evident coronary heart disease to reduce the risk of total mortality by reducing coronary death. In addition, this supplemental application provides for changes to the CLINICAL PHARMACOLOGY and PRECAUTIONS sections of the Pravachol package insert.

We have completed the review of this supplemental 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 agreed upon submitted labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted February 8, 2000).

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 "FPL for approved supplement NDA 19-898/S-032." 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 you have not fulfilled the requirements of 21 CFR 314.55. We are waiving the requirement for pediatric studies for the indication being approved in this supplemental application.

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

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 Management Officer, at (301) 827-6418.

Sincerely,

/S/

John K. Jenkins, M.D.
Acting Director
Division of Metabolic and Endocrine
Drug Products, HFD-510
Office of Drug Evaluation II
Center for Drug Evaluation and Research

APPEARS THIS WAY
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