DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-387

Bristol-Myers Squibb Company
Attention: Porter P. Layne, Ph.D.
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Layne:

Please refer to your new drug application (NDA) dated June 22, 2001, withdrawn on March 28, 2002, and resubmitted May 8, 2002, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Pravagard PAC (co-packaged 20, 40 or 80 mg pravastatin sodium and 81 or 325 mg buffered aspirin) Tablets.

We acknowledge receipt of your submissions dated March 13, April 18, May 20, 21 and 30 (two) and June 3, 2003

The May 30 and June 3, 2003 submissions constituted a complete response to our March 7, 2003 action letter.

This new drug application provides for the use of Pravagard PAC (co-packaged pravastatin sodium and buffered aspirin) to reduce the occurrence of cardiovascular events, including death, myocardial infarction or stroke, in patients who have clinical evidence of cardiovascular and/or cerebrovascular disease.

We have completed the review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the electronic final printed package insert, patient package insert and the immediate container and carton labels submitted on May 30, 2003.

At the time of the next printing, please make the following revisions to the labeling:

1. Change “hydroxypropyl methylcellulose” to “hypromellose” in the last sentence of the **DESCRIPTION/Buffered Aspirin** subsection.
2. Add “PAC” after “Pravagard” in the places throughout the labeling where it is currently absent.
3. Reduce the header font size of each subsection to be appropriate relative to the size of each section, e.g., **DESCRIPTION**(section)/**PRAVACHOL**(subsection).
4. Under the **INDICATIONS AND USAGE/PRAVIGARD** subsection, insert a comma after “stroke” in the second sentence.
5. Under the **INDICATIONS AND USAGE/PRAVACHOL/Hypercholesterolemia** subsection, add “LDL-C” after “Total-C” in the first sentence of the second paragraph.

We note that you have already submitted your proposed introductory promotional materials to the Division of Drug Marketing, Advertising, and Communications.

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 (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Meg Pease-Fye, Regulatory Health Project Manager, at (301) 594-5312.

Sincerely,

{See appended electronic signature page}

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Attachment

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Robert Temple
6/24/03 02:48:15 PM