DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 9-218/S-105

Bristol-Myers Squibb Company
Attention: David L. Silberstein, Associate Director
New Opportunities & Product Development
Pharmaceutical Research Institute
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Silberstein:

Please refer to your supplemental new drug application dated September 15, 2006, received September 18, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coumadin® (warfarin sodium) Tablets and Injection.

We acknowledge receipt of your submissions dated May 8, and August 13 and 16, 2007.

This supplemental new drug application provides for the revision of the Coumadin labeling to add pharmacogenomics information to the **CLINICAL PHARMACOLOGY, PRECAUTIONS** and **DOSAGE AND ADMINISTRATION** sections of the package insert (PI).

We completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the Medication Guide). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 9-218."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mrs. Diane Leaman, Regulatory Project Manager, at (301) 796-1424.

Sincerely,

{See appended electronic signature page}

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure: NDA 9-218/S-105 PI.

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

/s/

Rafel Rieves

8/16/2007 10:37:35 AM