DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 09-218/S-098

Bristol-Myers Squibb Pharma Company
Attention: Robert A. Barto, MBA
Regulatory Affairs Manager
Chestnut Run Plaza, Maple Run 2134
974 Centre Road
Wilmington, DE 19805

Dear Mr. Barto:

Please refer to your supplemental new drug application dated November 30, 2000, received December 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coumadin® Tablets (Warfarin Sodium Tablets, USP) and Coumadin® for Injection (Warfarin Sodium for Injection, USP).

We acknowledge receipt of your submission dated October 8, 2001. Your submission of October 8, 2001 constituted a complete response to our May 30, 2001 action letter.

This "Changes Being Effected" supplemental new drug application provides for additional new drug interactions and a modification of the WARNINGS, Lactation section. These changes are in the following sections of the package insert: CLINICAL PHARMACOLOGY, PRECAUTIONS, WARNINGS, and DOSAGE AND ADMINISTRATION.

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 products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted October 8, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

In addition, please submit three copies of the introductory promotional materials that you propose to use for these products. 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 inserts 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 Professional" 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 Cheryl Perry, RN, BSN, Regulatory Project Manager, at (301) 827-7475.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, MD, MPH
Deputy Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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

/s/

Joyce Korvick
5/3/02 04:31:03 PM