DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 09-218/S-099

Bristol-Myers Squibb Pharma Company
Attention: Robert A. Barto, MBA
Regulatory Affairs Manager
Chestnut Run Plaza, Maple Run 2134
974 Centre Road
Wilmington, DE 19805-1269

Dear Mr. Barto:

Please refer to your supplemental new drug application dated November 27, 2001, received November 28, 2001, 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).

This supplemental new drug application provides for labeling changes in the PRECAUTIONS section of the package insert to reflect the potential for Coumadin® interactions with antifungal drugs administered intravaginally, i.e. creams and suppositories.

We have completed the review of this supplemental application 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 agreed upon 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 November 27, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 09-218/S-099." Approval of this submission by FDA is not required before the labeling is used.

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, Regulatory Health 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
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