CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 09-218/S097

APPROVAL LETTER

NDA 09-218/S-097

FEB 17 2000

DuPont Pharmaceuticals Company
Attention: James L. Gaskill, R.Ph.
Chestnut Run Plaza, MR2146
974 Centre Road
Wilmington, DE 19805

Dear Mr. Gaskill:

Please refer to your supplemental new drug application dated November 12, 1999, received November 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Coumadin® (Warfarin Sodium Tablets, USP) Tablets and Coumadin® (Warfarin Sodium for Injection, USP) for Injection.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following: in the PRECAUTIONS section, the "EXOGENOUS FACTORS" subsection (factors that may be responsible for INCREASED PT/INR response), the "Specific Drugs Reported" table, the addition of the drug names "celecoxib", "rofecoxib", and "capecitabine". Your submission stated January 4, 2000 as the implementation date for the changes.

We have completed the review of this supplemental application 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 submitted final printed labeling submitted November 12, 1999. Accordingly, the supplemental application is approved effective on the date of this letter.

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

APPEARS THIS WAY
ON ORIGINAL

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, contact Karen Oliver, Regulatory Health Project Manager, at (301) 827-7457.

Sincerely,

/S/ 2-17-00

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

APPEARS THIS WAY
ON ORIGINAL

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 09-218/S097

APPROVABLE LETTER

NDA 9-218/S-097

DuPont Pharmaceuticals Company
Attention: James L. Gaskill, R.Ph.
Chestnut Run Plaza, MR2146
974 Centre Road
Wilmington, Delaware 19805

NOV 29

Dear Mr. Gaskill:

We have received your supplemental application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Coumadin® (Warfarin Sodium Tablets) Tablets
Coumadin® (Warfarin Sodium for Injection) for Injection
NDA Number: 9-218

Supplement Number: S-097

Date of Supplement: November 12, 1999

Date of Receipt: November 17, 1999

This supplemental application, submitted as "Supplement – Changes Being Effected" proposes the following change: in the PRECAUTIONS section, the "EXOGENOUSE FACTORS" (factors that may be responsible for INCREASED PT/INR response), the "Specific Drugs Reported" table, the following drug names have been added: celecoxib, rofecoxib, and capecitabine. In your submission you state that the change to the package insert will be implemented January 4, 2000.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on January 16, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Gastrointestinal and Coagulation Drug Products, HFD-180
Attention: Division Document Room, Rm. 6B-24
5600 Fishers Lane
Rockville, Maryland 20857

APPEARS THIS WAY
ON ORIGINAL

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