DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-262 / S-026, S-027, S-028

April 9, 1998

Bristol-Myers Squibb Pharmaceutical Research Institute
5 Research Parkway - P.O. Box 5100
Wallingford, CT 06492-7660

Attention: Cheryl L. Anderson
Director, Worldwide Regulatory Affairs

Dear Ms. Anderson:

Please refer to your supplemental new drug applications dated October 7, November 19 and 18, 1997, received October 9, November 20 and 21, 1997, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxol (paclitaxel) Injection, 30 mg/5 mL and 100 mg/16.7 mL.

We acknowledge receipt of your submissions and correspondences to S-026 dated October 20, 23, and 27, December 22, 1997, January 15, February 2, 3, 9, 19, and 25, March 10, and 12, and April 1 and 6, 1998. We also acknowledge receipt of your amendment dated January 9, 1998, containing final printed labeling (FPL), for supplemental applications S-027 and S-028 and the correspondence to S-027 dated January 13, 1998. We note that the submissions to S-027 and S-028 have been superseded by the February 19, 1998 submission to S-026. Therefore, the submissions to S-027 and S-028 will not be reviewed, but they will be retained in our files.

The User Fee goal dates for these applications are April 9, May 20 and 21, 1998.

Supplemental application S-026 provides for the use of Taxol as first-line therapy for the treatment of advanced carcinoma of the ovary in combination with cisplatin. Supplemental application S-027 provides labeling changes to the ADVERSE REACTIONS section, and supplemental application S-028 provides labeling changes to the DESCRIPTION, DOSAGE AND ADMINISTRATION: Stability, HOW SUPPLIED: Storage sections.

We have completed the review of these supplemental applications, including the submitted draft labeling, 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 enclosed modified draft labeling. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed modified draft labeling.

Please submit 20 copies of the FPL as soon as it is available, in no case 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 "FINAL PRINTED

LABELING" for approved supplemental NDAs 20-262 / S-026, S-027, S-028. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Oncology Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising
and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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 set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Dianne Spillman, Project Manager, at (301) 594-5746.

Sincerely yours,

Robert J. DeLap, M.D., Ph.D.
Director
Division of Oncology Drug Proucts
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE