DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-262/S-036/S-037/S-038

Bristol-Myers Squibb Company
5 Research Parkway
Wallingford, CT 06492

Attention: Susan H. Behling, Director
Oncology Global Strategic Unit, Worldwide Regulatory Affairs

Dear Ms. Behling:

Please refer to your supplemental new drug application dated August 8, 2000 (S-038), received August 9, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxol (paclitaxel) Injection.

We also refer to your supplemental new drug application dated May 11 (S-037), received on May 12, 2000 and your final printed labeling (FPL) for S-036 dated July 6, received on July 7, 2000.

The "Changes Being Effected" supplemental new drug application 037 dated May 11, 2000, provides for changes to the **ADVERSE REACTIONS** section of the package insert by incorporating ototoxicity into the list of adverse events reported during continuing surveillance of Taxol safety. The submission dated July 6, 2000, provides final printed labeling in follow-up to the Approval letter dated June 20, 2000, for supplement 036. Both of these supplements have been superseded by supplement 038 and will be Acknowledged and Retained.

The "Changes Being Effected" supplemental new drug application 038 provides for changes to the **ADVERSE REACTIONS** section of the package insert by incorporating Steven's Johnson Syndrome and toxic epidermal necrolysis to the list of adverse events reported during the continuing surveillance of Taxol safety.

We have completed the review of supplemental application 038 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 (package insert and patient package insert submitted on August 8, 2000. 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 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 Christy Wilson, Consumer Safety Officer, at (301) 594-5761.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
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/

Richard Pazdur

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