DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-262/S-035

Bristol-Myers Squibb Company
Route 206 & Province Line Road
Princeton, NJ 08543

Attention: Steven Knapp
Executive Director, Marketed Products
Global Regulatory Science

Dear Mr. Knapp:

Please refer to your supplemental new drug application dated August 25, 1999, received August 26, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxol® (paclitaxel) for Injection.

We also acknowledge receipt of your submissions dated March 21 and June 13, 2002.

This supplemental new drug application provides for proposed draft labeling addressing the geriatric use of Taxol® in accordance with 21 CFR 201.57(f)(10).

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 product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

> On page 18 of the labeling, there remains a single word processing error. In "Estimates of efficacy appeared similar in elderly patients and in younger patients; however, this comparative efficacy cannot be determined..." the word "this" should be deleted.

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the submitted draft labeling (package insert and patient package insert submitted June 13, 2002). These revisions are terms of the approval of this application.

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 20-262/S-035." 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 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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