



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-262 / S-024

June 30, 1998

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

Attention: Susan H. Behling
Director, U.S. Liaison
Worldwide Regulatory Affairs

Dear Ms. Behling:

Please refer to your supplemental new drug application dated June 30, 1997, received June 30, 1997, and submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Taxol (paclitaxel) Injection, 30 mg/5 mL, 100 mg/16.7 mL, and 300 mg/50 mL.

We acknowledge receipt of your submissions and correspondences dated July 15, August 15 and 19, September 17 and 26, October 14 and 27, November 12, December 2, 9, 17, and 22, 1997; January 19 and 21, February 9, 19, 20, and 24, March 13 and 18, May 5, and June 18, 1998. The User Fee goal date for this application is June 30, 1998.

This supplemental new drug application provides for the use of Taxol (paclitaxel) Injection, in combination with cisplatin, for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.

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 enclosed 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 enclosed labeling (text for the package insert). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 "FPL for approved supplement 20-262/S-024." Approval of this submission by FDA is not required before the labeling is used.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

We recommend that you evaluate whether there is a gender effect on the pharmacokinetics of paclitaxel at 135 mg/m² given as a 24 hour infusion in non small cell lung cancer patients. Any protocols, data, and final reports addressing this recommendation should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. For administrative purposes, all submissions, including labeling supplements, relating to this recommendation should refer to this supplement.

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 this Division and two copies of both the promotional materials and the package insert directly to:

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

If a letter communicating important information about this drug product (i.e., a “Dear Healthcare 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

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 L. Justice, M.D.
Acting Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE