DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020262/S-048 **SUPPLEMENT APPROVAL**

Bristol-Myers Squibb Company
Attention: Beatrice Anduze-Faris, M.D.
Group Director, Mature Products, Global Regulatory Sciences
Bristol-Myers Squibb
P.O. Box 4000 (Mailstop D12-02)
Princeton, MJ 08543-4000

Dear Dr. Anduze-Faris:

Please refer to your supplemental new drug application dated November 21, 2007, received November 21, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Taxol® (paclitaxel) for Injection 30 mg, 100 mg, and 300 mg.

We also refer to your submission dated May 14, 2010.

This "Changes Being Effected" supplemental new drug application provides for

- revised statement regarding TAXOL use with inducers, substrates, or inhibitors for cytochrome P450 isoenzymes in PRECAUTIONS: Drug Interactions section
- added statement regarding monitoring of cardiac function when TAXOL is used with Doxorubicin in PRECAUTIONS: Cardiovascular section
- updating of the ADVERSE REACTIONS: Respiratory, Neurologic, Renal, Gastrointestinal, and Other Events subsections with new information
- added statements regarding opportunistic infections, and elevated liver function tests and renal toxicity in Kaposi's sarcoma patients to ADVERSE Event Experiences by Body System section;
- added additional adverse events when TAXOL is combine with other chemotherapy, notably anthracyclines, in ADVERSE REACTIONS: Adverse Event Experiences by Body System – Cardiovascular and Other Clinical Events section;
- added safe handling of primary package to the HOW SUPPLIED: Handling and Disposal section
- updating of the REFERENCES
- added test to PATIENT INFORMATION section
- minor editorial changes were made to the package insert
- removal of Bristol-Myers Squibb Oncology logo

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, text for the patient package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

Submit final printed labeling, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (package insert, patient information), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)". Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "Final Printed Labeling for approved NDA 020262/S-048." Approval of this submission by FDA is not required before the labeling is used.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing,

Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lisa Skarupa, Regulatory Project Manager, at (301) 796-2219.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20262	SUPPL-48	BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE	TAXOL (PACLITAXEL) INJ

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

AMNA IBRAHIM
08/13/2010