DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

MAY 4 1998

TRANSMITTED VIA FACSIMILE

Jeffrey T. Whitmer, M.D., Ph.D.
Director, Regulatory Affairs and Promotional Compliance
Bristol-Myers Squibb Company
P.O. Box 4500
Princeton, NJ 08543-4500

Re: NDA 20-262
TAXOL (paclitaxel)
Macmis # 6512

Dear Dr. Whitmer:

This letter is in reference to Bristol Myers Squibb's March 20, 1998, press release regarding the Oncologic Drugs Advisory Committee meeting for Taxol regarding treatment of non-small-cell lung cancer (NSCLC). The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this material and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

The press release is misleading because it presents promotional claims of safety and efficacy for Taxol for uses for which it is under investigation. Further, the press release overstates the efficacy data and suggests that Taxol is useful in a broader range of conditions than indicated. Examples include but are not limited to the following statements:

- "Based on the clinical benefit derived in late stage disease, regimens of Taxol plus a platinum agent are being combined with radiation therapy in earlier disease stages with very encouraging preliminary results." "Promising new studies indicate that Taxol-based regimens provide increased clinical benefits when used in combination with radiation in earlier stages of disease."

- "These data confirm that Taxol, when combined with a platinum agent, results in higher response rates and increased survival and quality of life benefits compared to standard cisplatin-based combination regimens." "The (three) studies showed overall clinical benefit ..., increased time to disease progression, symptom alleviation,

quality of life and safety, with survival as good as or better than the standard regimen."

In the clinical studies for NSCLC, Taxol was studied in combination with only one platinum agent (cisplatin). Thus, it is misleading to suggest that Taxol is indicated in combination with any "platinum" agent.

Further, the majority of Advisory Committee members voted that two of the three studies would not serve as adequate and well-controlled trials demonstrating the efficacy and safety of a 175 mg dose of Taxol as a 3-hour infusion in combination with cisplatin for the treatment of NSCLC in patients who are not candidates for potentially curative surgery and/or radiation therapy. The studies involving these dosage regimens did not demonstrate statistically significant differences in survival or time to tumor progression.

Therefore, this violative promotion of Taxol should be discontinued immediately. BMS should respond to this letter by May 18, 1998, indicating its intent to comply with this recommendation. This response should include a list of all similarly violative materials and a description of the method for discontinuing their use.

If BMS has any questions or comments, please contact the undersigned by facsimile at (301)594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857. In all correspondence related to this matter, please refer to MACMIS ID #6512, in addition to the NDA number.

Sincerely,

Anne M. Reb, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications