

January 28, 2002

Bedford Laboratories
Attention: Molly Rapp
270 Northfield Road
Bedford, Ohio 44146

Sent by Facsimile and U.S. Mail

Dear Ms. Rapp:

This is in reference to your abbreviated new drug application dated August 21, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Paclitaxel Injection, 6 mg/mL (packaged in 30 mg/5 mL, 100mg/16.7 mL, and 300 mg/50 mL multiple-dose vials).

Reference is also made to your amendments dated October 20, 1999; June 16, 2000; and January 24, May 15, May 25, May 30, June 8, June 13, and July 25, 2001, your approval letter dated July 27, 2001, any intervening supplements that were approved, and the rescission of your approval and Tentative Approval dated January 25, 2002.

The listed drug product referenced in your application, Taxol® Injection of Bristol Myers Squibb Co. Pharmaceutical Research Institute, is subject to periods of patent protection which expire on August 3, 2012, [U.S. Patent No. 5,641,803 (the '803 patent), and U.S. Patent No. 5,670,537 (the '537 patent)]; May 08, 2001, [U.S. Patent No. 6150398 (the '398 patent); and March 9, 2013 [U.S. Patent No. 5,496,804 (the '804 patent)]. Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Paclitaxel Injection will not infringe on the '803, '804, or '537 patents. Your application also contains a statement under Section 505(j)(2)(A)(viii) of the Act indicating that the '398 patent is a methods of use patent, and that your labeling does not claim the indications or methods of use covered by this patent. You have informed the Agency that Bedford Laboratories has complied with the requirements of Section 505(j)(2)(B) of the Act and that

Bristol Myers Squibb Co. Pharmaceutical Research Institute initiated a patent infringement suit against you in the United States District Court for the District of New Jersey with respect to the '803 and '537 patents (Bristol Myers Squibb Company v. Boehringer Ingelheim Corp., Ben Venue Laboratories, Inc. and Bedford Laboratories, Civil Action No. 97CV-6050(WHW)). The Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

Taxol® is also covered by periods of Waxman-Hatch exclusivity, D-57, I-270, I-226 and I-230; and Orphan Drug Exclusivity (ODE) that are listed in Approved Drug Products with Therapeutic Equivalence Evaluations, 21st Edition (Orange Book). You have made a statement that your labeling for paclitaxel injection does not claim the indications or methods of use covered by such exclusivity.

Please note that on January 17, 2002, Bristol Myers Squibb withdrew the listing of U.S. Patent No. 6,096,331. This patent is no longer listed in the Orange Book for Taxol®, the RLD identified in your ANDA. Therefore, you are not required to submit a certification under section 505(j)(2)(A)(vii) of the Act for this patent.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Paclitaxel Injection, 6 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Taxol® Injection, 6 mg/mL, of Bristol Myers Squibb Co. Pharmaceutical Research Institute).

Under Section 506A of the Act, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the changes may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy that you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research