

September 15, 2000

Baker Norton Pharmaceuticals, Inc.
Attention: Steven M. Viti, Ph.D.
4400 Biscayne Blvd.
Miami, FL 33137

Dear Sir:

This is in reference to your abbreviated new drug application dated July 30, 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, 150 mg/25 mL, and 300 mg/50 mL multiple-dose vials).

Reference is also made to the Tentative Approval letter issued by this office on August 28, 2000, and to your amendments dated September 8, and September 14, 2000.

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)]; 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 or '537 patents. Your application also contains a patent statement under Section 505(j)(2)(A)(viii) of the Act indicating that the '804 patent is a method of use patent, and that this patent does not claim any of the proposed indications for which you are seeking approval. You have informed the Agency that Baker Norton Pharmaceuticals, Inc. 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. Baker Norton Pharmaceuticals, Inc. and Ivax Corporation, Civil Action No. 97-6050). 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.

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 change 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
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research

