

ANDA 75-184

August 28, 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 your amendments dated June 23, July 14, July 25, August 7, August 8, August 21, August 22, and August 24, 2000.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention.

The listed drug product (RLD) 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)], March 9, 2013 [U.S. Patent No. 5,496,804 (the '804 patent)], and February 22, 2013 [U.S. Patent No. 6,096,331 (the '331 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 this drug product will not infringe on the '803, '537, or '331 patents.

In addition, your application 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. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by the owner of the new drug application (NDA) for the referenced listed drug product and the patent holder. You have notified FDA that Baker Norton Pharmaceuticals, Inc. complied with the requirements of Section 505(j)(2)(B) of the Act with respect to the '803 and '537 patents. As a result, Bristol-Myers Squibb Co. initiated a patent infringement suit involving these patents against Baker Norton Pharmaceuticals, Inc. and Ivax Corporation in the United States District Court for the District of New Jersey (Bristol-Myers Squibb Company v. Baker Norton Pharmaceuticals, Inc. and Ivax Corporation, Civil Action No. 97-6050). You have also notified the Agency that with respect to the suit mentioned above, the 30-month period during which the Agency was precluded from approving this application expired on June 2, 2000. Thus, final resolution of the approval status of this application can not be concluded until all legal and regulatory issues surrounding your challenge of the '331 patent have been satisfactorily resolved.

In order to reactivate your application prior to final approval, please submit an amendment at least 60 days prior to the date you believe the application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing and controls data as appropriate. Alternatively, a statement should be provided stating that no changes have been made to the term of the application since the date of this tentative approval letter. In addition, the final disposition of your certification to the '331 patent should be submitted. This amendment should be designated clearly in your cover letter as a MINOR amendment. In addition to, or instead of this amendment, the Agency may request at any time prior to the date of final approval of this application that you submit an amendment containing the information described above. Failure to submit either or, if requested, both amendments may result in rescission of the tentative approval status of your

application, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to the Agency review before final approval of the application will be made. The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug before the effective final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list.

Prior to submitting the amendment(s), please contact Elaine Hu, R.Ph., Project Manager, at (301) 827-5848, for further instructions.

Sincerely yours,

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

Research

