ANDA 75-297 March 27, 2001

Zenith Goldline Pharmaceuticals, Inc.
Attention: Karen Rocco
140 Legrand Avenue
Northvale, NJ 07647

Dear Madam:

This is in reference to your abbreviated new drug application dated December 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, 100 mg/16.7 mL, and 150 mg/25 mL multiple-dose vials).

Reference is also made to the Tentative Approval letter issued by this office on October 10, 2000, and to your amendments dated March 5, and March 14, 2001.

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], and March 9, 2013 [U.S. Patent No. 5,496,804 (the '804 patent)]. We note that U.S. Patent No. 6,096,331 also references Taxol Injection. However, in accordance with 21 CFR 314.94(a)(12)(vi), Zenith Goldline Pharmaceuticals, Inc. (Zenith Goldline) is not required to submit a certification to this 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 these patents. 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 Zenith Goldline has complied with the requirements of Section 505(j)(2)(B) of the Act and that Bristol-Myers Squibb initiated a patent infringement suit in the United States District Court for the District of New Jersey

(Bristol-Myers Squibb Company v. Zenith Goldline Pharmaceuticals, Inc. and Ivax Corporation, Civil Action No. 98-1412). You have also informed us that a judgement of invalidity was rendered on April 7, 2000 and that this judgement was appealed by Bristol-Myers Squibb Company to the Court of Appeals for the Third Circuit on April 17, 2000. The appellate proceeding remains pending.

With regard to the litigation, the Agency recognizes that the 30-month period identified in Section 505(j)(5)(B)(iii) of the Act during which time FDA is precluded from approving your application, has expired. Furthermore, we acknowledge that Baker Norton Pharmaceuticals, Inc. (BNPI), is the holder of 180-day exclusivity for this drug product in accordance with the Hatch-Waxman Amendments to the Act. We also acknowledge that on
March 5, 2001, BNPI selectively waived the remainder its exclusivity to Zenith Goldline.

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