ANDA 74-735 July 16, 1999

American Pharmaceutical Partners, Inc.
Attention: Genny Cruz
2045 North Cornell Avenue
Melrose Park, IL 60160-1002

Dear Madam:

This is in reference to your abbreviated new drug application dated August 24, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cisplatin Injection 1 mg/mL (packaged in multiple-dose vials containing 50 mg/50 mL, 100 mg/100 mL, and 200 mg/200 mL).

Reference is also made to our tentative approval letter dated July 29, 1997, and to your amendments dated April 29, May 28, June 11, and June 18, 1999.

The listed drug product (RLD) referenced in your application, Platinol-AQ Injection of Bristol Myers Co., is subject to a period of patent protection which expires on May 8, 2012, (U.S. Patent No. 5,562,925 [the '925 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 '925 patent and that the patent is invalid. Section 505(j)(5)(B)(iii) of the Act provides that approval of the application shall be made effective immediately, unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received by both the holder of the patent and holder of the new drug application (NDA) for the RLD. You have notified the Agency that the previous holder of this application and American Pharmaceutical Partners, Inc. have complied with the requirements of Section 505(j)(2)(B) of the Act. You have also notified the Agency that the '925 patent holder and the NDA holder initiated a patent infringement suit against the former holder of this application in the United States District Court for the Northern District of Illinois (Research Corporation Technologies, Inc., and Bristol Myers Squibb Company v. Fujisawa U.S.A., Inc., Civil Action No. 97C 0564). You have also notified the Agency that the 30-month period provided for in Section 505(j)(5)(B)(iii) of the Act, during which time FDA was precluded from approving your application, has expired.

This letter does not address notice issues related to the 180-day exclusivity provisions under Section 505(j)(5)(B)(iv) of the Act.

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 Cisplatin Injection, 1 mg/mL, (50 mg/50 mL and 100 mg/100 mL) to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Platinol®-AQ Injection, 1mg/mL, (50 mg/50 mL and 100 mg/100 mL) of Bristol Myers Co.). Your Cisplatin Injection, 1 mg/mL (200 mg/200 mL), can be expected to have the same therapeutic effect as that of the reference listed drug product upon which the Agency relied as the basis of safety and effectiveness.

Under 21 CFR 314.70, 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 which 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,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research