ANDA 74-656 May 16, 2000

Teva Pharmaceuticals USA
Attention: Deborah A. Jaskot
U.S. Agent for: Pharmachemie B.V.
1510 Delp Drive
Kulpsville, PA 19443

Dear Madam:

This is in reference to your abbreviated new drug application dated March 31, 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
10 mg/10 mL, 50 mg/50 mL, and 100 mg/100 mL.).

Reference is also made to our tentative approval letter dated May 29, 1997, and to your amendments dated May 12, and July 21, 1999, and January 12 and January 27, 2000.

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 the '925 patent is invalid and unenforceable. You have notified the Agency that Pharmachemie B.V. has complied with the requirements of Section 505(j)(2)(B) of the Act and that a patent infringement suit was initiated against Pharmachemie B.V. in the United States District Court for the Northern District of New Jersey (Bristol Myers Squibb Company and Research Corporation Technologies, Inc., v. Pharmachemie B.V., Civil Action No. 97-1452).

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 expired on August 4, 1999. However, the agency was unable to

grant final approval to your application on August 4, 1999, because an abbreviated application for the drug product containing a Paragraph IV Certification under Section 505(j)(2)(a)(vii)(IV) was previously approved by this office.

The applicant of the previously approved application, American Pharmaceutical Partners, Inc., became eligible for 180 days of generic drug exclusivity. We refer you to the agency's guidance document entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments" (June 1998) for additional information on this topic. As a result, your application became eligible for final approval beginning 180 days after the first commercial marketing of the drug product under the former application; i.e., May 15, 2000.

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, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Platinol®-AQ Injection, 1mg/mL, of Bristol Myers Co.).

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 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,

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