ANDA 74-814 May 16, 2000

Gensia Sicor Pharmaceuticals, Inc.
Attention: Elvia O. Gustavson
19 Hughes
Irvine, CA 92618-1902

Dear Madam:

This is in reference to your abbreviated new drug application dated December 22, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cisplatin Injection, 1 mg/mL, (packaged in 50 mL and 100 mL multiple-dose vials).

Reference is also made to your amendments dated February 8, March 2, and April 7, 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 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 Cisplatin Injection will not infringe on the '925 patent. You have notified the Agency that Bristol Myers Co. initiated a patent infringement suit against you in United States District Court for the Central District of California (Research Corporation Technologies, Inc. and Bristol-Myers Squibb Company v. Gensia Laboratories, Ltd., Civil Action No. 97-3992).

The Agency also 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 expired October 20, 1999. However, the Agency was unable to grant final approval to your application on October 20, 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 was American Pharmaceutical Partners, Inc., which 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, respectively, 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