ANDA 74-713

Bedford Laboratories
Attention: Shahid Ahmed
270 Northfield Road
Bedford, Ohio 44146

Dear Sir:

This is in reference to your abbreviated new drug application dated July 24, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Cisplatin for Injection USP, 10 mg/vial and 50 mg/vial.

Reference is also made to our Tentative Approval letter dated April 16, 1997 and to your amendment dated September 29, 2000.

The listed drug product (RLD) referenced in your application, Platinol® 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 the Cisplatin for Injection will not infringe on the '925 patent or that the patent is otherwise invalid. You have informed the agency that Research Corporation Technologies, Inc. and Bristol-Myers Squibb Company initiated a patent infringement suit against you in United States District Court for the Northern District of Ohio, Eastern Division (Research Corporation Technologies, Inc. and Bristol-Myers Squibb Company v. Ben Venue Laboratories, Inc., Civil Action No. 1:97CV00872). This case was subsequently consolidated with similar challenges to the '925 patent by other ANDA applicants and transferred to the United States District Court for the District of New Jersey [Civil Action No. 97-2836 (GEB)]. You have also informed the agency that Ben Venue Laboratories, Inc. and the other defendants prevailed in that litigation.

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 for Injection USP, 10 mg/vial and

50 mg/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Platinol® Injection, 10 mg/vial and 50 mg/vial, respectively, of Bristol Myers Co.). This letter does not address issues related to the 180-day exclusivity provisions under Section 505(j)(5)(B)(iv) of the Act.

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