ANDA 75-036 November 7, 2000

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

Dear Sir:

This is in reference to your abbreviated new drug application dated December 23, 1996, 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 our Tentative Approval letter dated December 29, 1998, and to your amendments dated March 4, 1997, and September 29, 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 the Cisplatin Injection will not infringe on the patent or that the patent is otherwise invalid. Subsequently, 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). You have informed the agency that Ben Venue Laboratories, Inc. 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 Injection, 1mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Platinol-AQ ® Injection, 1 mg/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