DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-611

APR 11 2006

Bedford Laboratories
Attention: Molly Rapp
Associate Director, Ben Venue Laboratories
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 26, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, packaged in 20 mg/10 mL, 25 mg/12.5 mL, and 30 mg/15 mL Multiple-dose vials.

Reference is also made to the Tentative Approval letter issued by this office on February 19, 2004, and to your amendments dated August 27, 2004; and January 12, February 24, March 2, March 7, March 24, and March 28, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Novantrone Injection (Concentrate), 2 mg/mL, of Serono, Inc.).

The reference listed drug product (RLD) referenced in your application, Novantrone Injection (Concentrate), 2 mg/mL, of Serono, Inc. has been subject to a period of patent protection. As noted in the agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book" U.S. Patent No. 4,617,319 (the '319 patent) expired on June 13, 2005, and U.S. Patent No. 4,820,738 (the '738 patent) expired on April 11, 2006.

Your ANDA contains paragraph III certifications to each of the listed patents under section 505(j)(2) (A)(vii)(III) of the Act. These certifications state that Bedford Laboratories will not market Mitoxantrone Injection USP, (Concentrate), 2 mg/mL, under this ANDA prior to the expiration of both of the listed patents. Since each patent has expired, the agency is no longer precluded from approving your application.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

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