DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-068

Food and Drug Administration
Rockville MD 20857

SEP 28 2004

Bedford Laboratories
Attention: Molly Rapp
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 21, 2000, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Dexrazoxane for Injection, 250 mg/single-dose vial and 500 mg/single-dose vial.

Reference is also made to your amendments dated October 7, November 21, December 29, 2003; and February 23, March 2, March 4, March 17, March 31, April 22, May 12, July 27, August 3, and August 12, 2004. We also acknowledge receipt of your correspondence dated December 5, 2002; March 6, 2003; and March 4, May 12, and July 27, 2004, addressing patent issues associated with this drug product.

The listed drug product referenced (RLD) in your application, Zinecard for Injection of Pharmacia & Upjohn Co., is subject to periods of patent protection. As noted in the Agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. patent 4,963,551 (the '551 patent) is scheduled to expire on December 21, 2007, and U.S. patent 5,242,901 (the '901 patent) is scheduled to expire on September 7, 2010. Your application contains paragraph IV certifications to the '551 and the '901 patents under Section 505(j)(2)(A)(vii)(IV) of the Act stating that these patents will not be infringed by your manufacture, use, or sale of Dexrazoxane for Injection under this ANDA. Section 505(j)(5)(B)(iii) of the Act provides that approval of an ANDA shall be made effective immediately, unless an action is brought against Bedford Laboratories (Bedford) for infringement of either the '551 or the '901 patents which were the subjects of the paragraph IV certifications. This action myst have been brought against Bedford prior to the expiration of 45 days from the date the notice Bedford provided to the NDA/patent holder(s)

under paragraph (2)(B)(i) was received. You have notified the Agency that Bedford complied with the requirements of Section 505(j)(2)(B) of the Act, and that Pharmacia and Upjohn, Co. (since acquired by Pfizer Inc.) initiated a patent infringement action regarding the '551 patent against you in the United States District Court for the District of New Jersey (Ben Venue Laboratories v Pharmacia Corporation, Civil Action No. 03-1039 (GEB)). You have also notified the Agency that on April 28, 2004, an Order of Dismissal was granted on the Complaint by the New Jersey District Court, and that Pfizer Inc. and Ben Venue/Bedford Laboratories reached a settlement in this matter. A Stipulation of Dismissal of the litigation was signed on July 14, 2004, by the United States District Court for the District of New Jersey. Furthermore, you have provided the Agency with a letter dated July 26, 2004, from Pfizer Inc. in which Pfizer states that it does not object to the Agency's approval of your ANDA for Dexrazoxane for Injection. You have also notified the Agency that no legal action was taken against Bedford Laboratories within the statutory 45 day period for infringement of the '901 patent.

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 Dexrazoxane for Injection, 250 mg/vial and 500 mg/vial, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug Zinecard® for Injection, 250 mg/vial and 500 mg/vial, respectively, of Pharmacia and Upjohn Co.

With respect to 180-day generic drug exclusivity, we note that Bedford Laboratories was the first ANDA applicant to submit a substantially complete ANDA containing paragraph IV certifications to the '551 and '901 patents for this drug product. Therefore, with this approval Bedford Laboratories is eligible for 180-days of market exclusivity for Dexrazoxane for Injection. This exclusivity will begin to run from the date Bedford Laboratories begins commercial marketing of the drug product.

With respect to the "first commercial marketing" trigger for the commencement of exclusivity, please refer to 21 CFR 314.107(c)(4). The Agency expects that you will begin commercial marketing of this drug product in a prompt manner. Please submit correspondence to your application stating the date you commence commercial marketing of this product.

If you have any questions concerning the effective date of approval of an abbreviated new drug application and the Agency's elimination of the requirement that an ANDA applicant successfully defend a patent infringement suit to be eligible for 180-days of marketing exclusivity, please refer to the interim rule published in the November 5, 1998 Federal Register (Volume 63, No. 214, 59710).

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.

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
Division of Drug Marketing, Advertising, and Communications, HFD-42
5600 Fishers Lane
Rockville, MD 20857

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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

(b)(6)

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