DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-992

AUG 28 2006

Bedford Laboratories
Attention: Molly L. Rapp
Associate Director, Regulatory Affairs
300 Northfield Road
Bedford, OH 44146

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 23, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ciprofloxacin Injection USP, 10 mg/mL, packaged in 200 mg/20 mL and 400 mg/40 mL single-dose vials.

Reference is also made to our Tentative Approval letter dated September 23, 2004, and to your amendments dated June 10, and November 19, 2004, and April 12, May 26, and June 30, 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 Ciprofloxacin Injection USP, 10 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Cipro I.V. Injection, 10 mg/mL, of Bayer Pharmaceuticals Corp.

The reference listed drug product (RLD) referenced in your application, CIPRO I.V., injection 10 mg/mL, packaged in 200 mg/20 mL and 400 mg/40 mL single-dose vials of Bayer Corporation Pharmaceutical Division 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. 4,808,583 (the '583 patent) expired on August 28, 2006.

Your ANDA contains a Paragraph III Certification to the '583 patent under section 505(j)(2) (A)(vii)(III) of the Act. This certification states that you will not market your Ciprofloxacin Injection USP, 10 mg/mL, packaged in 200 mg/20 mL and 400 mg/40 mL single-dose vials prior to the expiration of the patent. The agency recognizes the patent has expired, no longer precluding the agency 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.

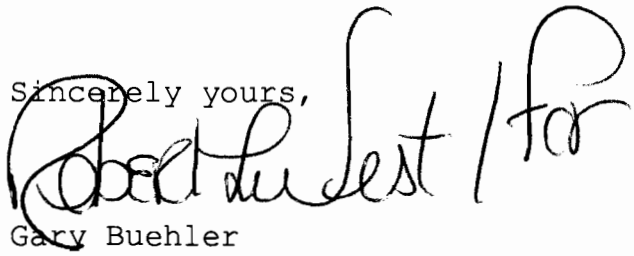
Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

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