DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

ANDA 76-484

AUG 28 2006

Abraxis Pharmaceutical Products
Attention: Kathleen Dungan
Senior Regulatory Scientist
6133 North River Road, Suite 500
Rosemont, IL 60018

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated August 30, 2002, 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-use vials.

Reference is also made to our tentative approval letter dated February 19, 2004, and to your amendments dated February 5, May 8, May 16, July 14, August 7, August 24, and August 25, 2006.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Ciprofloxacin Injection USP, 10 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Cipro I.V, Injection, 10 mg/mL, of Bayer Pharmaceuticals Corporation.

The listed drug product (RLD) referenced in your application, Bayer's Cipro I.V Injection, 10 mg/mL, is 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. 4,208,583 (the '583 patent) is scheduled to expire 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 Abraxis Pharmaceutical Products will not market Ciprofloxacin Injection USP, 10 mg/mL, under this ANDA prior to the expiration of the '583 patent. The agency recognizes the

'583 patent expired on August 28, 2006, and that it no longer precludes 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.

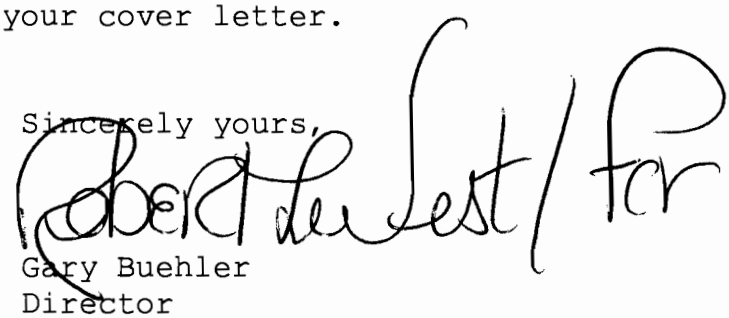
Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit,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

We remind you of your commitment specified in your amendment dated August 25, 2006. To alert the Office of Generic Drugs staff that you are submitting information to address the post-approval commitment, please state "Post- Approval Commitment Response" at the top of your cover letter.

Sincerely yours,



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