DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-558

Food and Drug Administration
Rockville MD 20857

JUN 9 2004

West-ward Pharmaceutical Corp.
Attention: Elizabeth A. Marro
U.S. Agent for: Hikma Pharmaceuticals
435/465 Industrial Way West
Eatontown, NJ 07724

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated December 3, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Ciprofloxacin Tablets USP, 250 mg, 500 mg, and 750 mg.

Reference is also made to the Tentative Approval letter issued by this office on March 2, 2004, and to your amendments dated March 25, April 22, June 8, and June 9, 2004.

We have completed the review of this tentatively approved 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 Ciprofloxacin Tablets USP, 250 mg, 500 mg, and 750 mg, to be bioequivalent and therefore, therapeutically equivalent to the listed drug, Cipro Tablets, 250 mg, 500 mg, and 750 mg, respectively, of Bayer Pharmaceuticals Corporation (Bayer). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

The listed drug product (RLD) referenced in your application, Cipro Tablets of Bayer Pharmaceuticals Corp., is subject to a period of patent protection. As noted in the agency's publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations, the "Orange Book", U.S. Patent 5,286,754 (the '754 patent) is scheduled to expire on August 15, 2011. Your application contains a

paragraph IV certification to the '754 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of Ciprofloxacin Tablets, USP under this ANDA will not infringe the '754 patent. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action is brought against Hikma Pharmaceuticals (Hikma) for infringement of the '754 patent prior to the expiration of 45 days from the date the notice you provided under Section 505 (j)(2)(B) was received by the owner of the new drug application (NDA) for the reference listed drug product and the patent holder. You have notified the agency that Hikma complied with the requirements of Section 505(j)(2)(B) of the act and that no action for infringement of the '754 patent was brought against Hikma within the statutory 45 day period.[1]

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

1- Because information on the `754 patent was submitted before August 18, 2003, the references are to sections of the Act as in effect prior to December 8, 2003, when the Medicare Prescription Drug, Improvement and Modernization Act (NMA) (Public Law 108-173) was enacted. See MMA § 1101(c)(3).

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) [redacted]

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