ANDA 65-264

Food and Drug Administration
Rockville MD 20857

MAY 19 2006

Lupin Pharmaceuticals, Inc.
U.S. Agent for: Lupin Limited
Attention: Vinita Gupta
Harborplace Tower, 21st Floor
111 South Calvert Street
Baltimore, MD 21202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated September 28, 2004, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Cefdinir Capsules, 300 mg. We note that this product is subject to the exception provisions of section 125(d)(2) of Title I of the Food and Drug Administration Modernization Act of 1997.

Reference is also made to your amendments dated January 27, 2005, August 23, 2005, October 6, 2005, and October 28, 2005.

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 Cefdinir Capsules, 300 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Omnicef® Capsules 300 mg of Abbott Laboratories). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in 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 (HFD-42) with a completed Form FDA 2253 at the time of their initial use.

FDA's field staff has not completed the validation of the regulatory methods submitted in your application. It is the policy of the Office of Generic Drugs to proceed with approval of your application while this process continues. We acknowledge receipt of your commitment to cooperate with the agency to resolve any methods validation related deficiencies which may be identified.

Sincerely yours,

Robert L West / for

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