DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 75-677

Food and Drug Administration
Rockville MD 20857

SEP 28 2005

Apotex Corp.
U.S. Agent for: Apotex Inc.
Attention: Kalpesh Sharoff
2400 N. Commerce Parkway, Suite 400
Weston, FL 33326

Dear Sir:

This is in reference to your abbreviated new drug application (ANDA) July 27, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Acyclovir Capsules USP, 200 mg.

Reference is also made to your amendments dated January 21, July 27, September 1, and September 8, 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 Acyclovir Capsules USP, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Zovirax® Capsules USP, 200 mg, of GlaxoSmithKline). 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 abbreviated application require an approved supplemental application before the change may be made.

Postmarketing 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
5901-B Ammendale Road
Beltsville, MD 20705-1266

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,

Robert Lee Lest / for

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