DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-089/S-020
NDA 19-909/S-022
NDA 18-828/S-031

GlaxoSmithKline
Sherman N. Alfors
Director, Antiviral/Antibacterial
P.O. box 13398
Five Moore Drive
Research Trianagle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug applications dated October 27, 2007, received October 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax® (acyclovir) Capsules, Zovirax® (acyclovir) Tablets and Zovirax® (acyclovir) Suspension.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the inclusion of renal pain in the Observed During Clinical Practice subsection of ADVERSE REACTIONS.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Products and two copies of both the promotional materials and the package inserts 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 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Tanima Sinha, M.S., Regulatory Project Manager, at (301) 796-0812.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray
8/8/2008 09:40:08 AM