DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-487/S-013 **CBE-30/CBE-0 SUPPLEMENT**

GlaxoSmithKline
Attention: Sherman N. Alfors
Director, Anitviral/Antibacterial
P.O. Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated October 25, 2007, received October 25, 2007, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for Valtrex® (valacyclovir hydrochloride) Caplets.

This "Changes Being Effected" supplemental new drug application provides for:

- ***Update to the U.S. package insert to include 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, for use as recommended in the agreed-upon labeling text.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, call Paras M. Patel, R.Ph., Regulatory Project Manager, at (301) 796-0783.

Sincerely,

{See appended electronic signature page}

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

Enclosure (Approved Labeling)

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

12/11/2007 10:29:41 AM