DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-487/S-007

GlaxoSmithKline
Attention: Sherman N. Alfors, Director
Antiviral/Antibacterial US Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated August 24, 2005, received August 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex® (valacyclovir hydrochloride), Caplets, 500 mg and 1000 mg for treatment and suppression of Herpes Zoster, Genital Herpes and Herpes Labialis.

This "Changes Being Effected" supplemental new drug application updates the PRECATIONS section and the Information for Patients subsection to include more descriptive information regarding the importance of maintaining adequate hydration.

We have completed out review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the submitted final printed labeling (FPL) submitted with the supplement.

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 Victoria Tyson-Medlock, Regulatory Project Manager, at (301) 796-0827.

Sincerely,

{See appended electronic signature page}

Enclosure:

Debra Birnkrant, M.D.
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/

Debra Birnkrant
11/23/2005 09:47:22 AM
NDA 20-487