DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-828/SLR-029
NDA 19-909/SLR-019
NDA 20-089/SLR-018

GlaxoSmithKline
Attention: Grace A. Pagano, MS
Associate Director, Antiviral/Antibacterial Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Ms. Pagano

Please refer to your supplemental new drug applications dated December 3, 2003, received December 4, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOVIRAX® (acyclovir) Capsules, Suspension, and Tablets.

These "Changes Being Effected" supplemental new drug applications provide for the revision of the labeling to add dysarthria to the Observed During Clinical Practice subsection of ADVERSE REACTIONS.

We completed our review of these supplemental new drug applications. They are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 3, 2003.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Nitin Patel, R.Ph., Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
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
5/19/04 02:22:26 PM