DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 18-828/S-030
NDA 20-089/S-019
NDA 19-909/S-020

GlaxoSmithKline
Attn: Grace A. Pagano
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709

Dear Ms. Pagano:

Please refer to your supplemental new drug applications dated August 16, 2005, received August 17, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOVIRAX® (acyclovir) Capsules, Tablets, and Suspension.

These "Changes Being Effected" supplemental new drug applications update the package insert to include statements under the PRECAUTIONS section to provide more descriptive information regarding the importance of maintaining adequate hydration.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the proposed labeling submitted with the supplement.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 David Araojo, Regulatory Project Manager, at (301) 796-0669.

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

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

12/9/2005 04:51:29 PM