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/
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Jeffrey Murray
12/9/2005 04:51:29 PM