DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-604/S-019

GlaxoSmithKline
Attention: Kevin A. Miller, R.Ph., RAC
Assistant Director, CMC Regulatory Affairs
PO Box 13398
Five Moore Drive
Research Triangle Park, NC 27709-3398

Dear Mr. Miller:

Please refer to your supplemental new drug application dated May 21, 2002, received May 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOVIRAX® (acyclovir) Topical Ointment, 5%.

We acknowledge receipt of your submissions dated August 5, 2002, and November 20, 2002.

This "Changes Being Effected" supplemental new drug application provides for a new sample presentation (1.5 g tube), to be distributed by (b) (4)

We have completed the review of this supplemental application, and it is approved.

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, please call Karen A. Young, RN, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Paul Miller
11/22/02 03:28:46 PM
NDA 18-604 S-019 is approved