



NDA 21-478/S-003

GlaxoSmithKline  
Kevin A. Miller, R.Ph., RAC  
Associate Director, CMC Regulatory Affairs  
Five Moore Drive  
Research Triangle Park, NC 27709-3398

Dear Mr. Miller:

Please refer to your supplemental new drug application dated July 24, 2003, received July 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ZOVIRAX<sup>®</sup> (acyclovir) Cream, 5%.

We acknowledge receipt of your submissions dated December 22, 2003, and January 19, 2004.

This "Changes Being Effected in 30 days" supplemental new drug application provides for a 0.9g foil sachet sample presentation of ZOVIRAX<sup>®</sup> Cream 5%.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (immediate container and display tray submitted July 24, 2003; revised folder submitted January 19, 2004).

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Antiviral Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the reporting requirements for an approved NDA (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}*

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/

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Stephen Paul Miller  
1/23/04 10:35:05 AM  
NDA 21-478 / S-003 is approved