



NDA 20-487/S-005

GlaxoSmithKline  
Attention: Sherman N. Alfors  
Director, Antiviral/Antibacterial  
US Regulatory Affairs  
PO Box 13398  
Five Moore Drive  
Research Triangle Park  
North Carolina 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated February 19, 2004, received February 20, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex® (valacyclovir hydrochloride) 500 mg and 1000 mg Caplets.

We acknowledge receipt of your submissions dated September 7, 2004 and November 11, 2004.

This supplemental new drug application provides for the revision of the PRECAUTIONS: Nursing Mothers subsection of the labeling for this drug product. The proposed wording is based on the results of a study which you have provided. Results from this study reported serum and human breast milk concentrations, ratios of serum to milk at different time points, as well as acyclovir concentrations from infant urine following maternal administration of Valtrex®.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 11, 2004.

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

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Jeffrey Murray  
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