DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-550/S-012

GlaxoSmithKline
Attention: Elizabeth Austin, Ph.D.
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Austin:

Please refer to your supplemental new drug application dated August 30, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex™ (valacyclovir hydrochloride).

We acknowledge receipt of your submissions dated:

October 27, 2000	December 12, 2000	February 26, 2001
November 9, 2000	December 15, 2000	March 19, 2001 (2)
November 22, 2000	January 26, 2001 (2)	May 10, 2001 (2)

This supplemental new drug application provides for a labeling indication for a shorter treatment course of three days in the treatment of recurrent episodes of genital herpes.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text with the following minor editorial revision listed below. Accordingly, these supplemental applications are approved effective on the date of this letter with the following minor revision, as discussed with Dr. Austin on June 19, 2001:

In the **VIROLOGY** section, under Drug Resistance, the first sentence of the second paragraph will read:

"Resistance of HSV and VZV to acyclovir occurs by the same mechanisms."

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 10, 2001) and must include the revision stated above. This revision is a term of the approval of this application.

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but

no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 20-550/S-012." Approval of these submissions by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). Please note we are waiving the pediatric study requirements for this indication for the following reasons: 1) we do not perceive a substantial medical need for treatment of recurrent genital herpes in the pre-pubertal population, and 2) data from the adult studies can be extrapolated for the adolescent population.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
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, please call Karen A. Young, RN, BSN, at 301-827-2335.

Sincerely,

{See appended electronic signature page}

Debra B. Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Attachment