DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-550/S-016

GlaxoSmithKline
Attention: Sherman N. Alfors
Associate Director Antiviral/Antibacterial Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Mr. Alfors:

Please refer to your supplemental new drug application dated November 13, 2001, received November 14, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex (valacyclovir hydrochloride).

We acknowledge receipt of your submissions dated June 7, 2002, June 28, 2002, July 16, 2002, and August 2, 2002.

This supplemental new drug application provides for the use of Valtrex (valacyclovir hydrochloride) for the treatment of cold sores (herpes labialis) in adult and adolescent patients 12 years of age and older.

We have completed the review of this supplemental application, 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, this supplemental application is approved effective on the date of this letter with the following minor revision, as discussed with Mr. Sherman Alfors on August 20, 2002:

In the **PRECAUTIONS** section, in the last paragraph, the words "see WARNINGS", will be added in parentheses. The paragraph will read:

"The safety and efficacy of VALTREX have not been established in immunocompromised patients (see WARNINGS), or for the treatment of disseminated herpes zoster."

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 2, 2002) 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 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, this submission should be designated "FPL for approved supplement NDA 20-550/S-016." Approval of this submission 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). We are waiving the pediatric study requirement for this action on this application.

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

Please submit one market package of the drug product when it is available.

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) 827-2376.

Sincerely yours,

{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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Debra Birnkrant
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NDA 20-550