DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-603/S-023, S-024, S-025

GlaxoSmithKline
Attention: Beth Austin, Ph.D.
Project Director, Regulatory Affairs
Five Moore Drive
P.O. Box 13398
Research Triangle Park, NC 27709

Dear Dr. Austin:

Please refer to your supplemental new drug applications dated April 24, 2000 (S-023), August 24, 2000 (S-024), and October 30, 2001 (S-025) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Zovirax® (acyclovir sodium) for Injection.

We acknowledge receipt of your submissions dated November 1, 2000, November 2, 2000, November 8, 2001, November 21, 2001, and December 10, 2001.

Your "Special Supplement: Changes Being Effected, Labeling" supplemental new drug application (S-023) provides for the addition of hepatitis, jaundice, and photosensitive rash to the Observed During Clinical Practice subsection of ADVERSE REACTIONS and updates the OVERDOSAGE, WARNINGS, and PRECAUTIONS: Pregnancy sections to agree with the labeling for Zovirax Capsules, Tablets, and Suspension (NDA 18-828/S-022 and S-024, 20-089/S-012, and NDA 19-909/ S-014) as approved on March 15, 2000.

Your supplemental new drug application (S-024) provides for labeling revisions written to comply with the provisions of the Geriatric labeling requirements promulgated on August 27, 1997 under 21 CFR 201.57(f)(10)(ii)(A) and (iii)(B).

Your "Special Supplement: Changes Being Effected, Labeling" supplemental new drug application (S-025) provides for the addition of angioedema, hyperbilirubinemia, aggressive behavior, ataxia, paresthesia, and severe local inflammatory reactions under the PRECAUTIONS, ADVERSE REACTIONS, and OVERDOSAGE sections.

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. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted December 10, 2001). 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 10 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 18-603/S-023, S-024, S-025." Approval of these submissions by FDA is not required before the labeling is used.

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, Regulatory Project Manager, at (301) 827-2376.

Sincerely yours,

{See appended electronic signature page}

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

Attachment

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 18-603 SLR 025, 024, 023