DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18603/S-030

SUPPLEMENT APPROVAL

GlaxoSmithKline, LLC
Attention: Jaisri Giridhar, PhD RAC
Manager, Global Regulatory Affairs
Five Moore Drive
PO BOX 13398
Research Triangle Park, NC 27709

Dear Dr. Giridhar:

Please refer to your Supplemental New Drug Application (sNDA) dated October 12, 2018 received October 12, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for ZOVIRAX® (acyclovir sodium) injection, for intravenous use, 500 mg and 1000 mg vials.

This "Changes Being Effected" supplemental new drug application provides for revisions to the:

- DOSAGE AND ADMINISTRATION, Neonatal Herpes Simplex Virus (HSV) subsection to include dosing in neonatal patients with herpes simplex virus infection based on post menstrual age (PMA). Changes to the dosing regimen in neonates were supported by pharmacokinetic data in term and preterm neonates, and by the safety and efficacy results from Study 2, an open-label clinical trial that evaluated ZOVIRAX in neonates with suspected HSV infection.
- CLINICAL PHARMACOLOGY, Special Populations, Pediatrics; CLINICAL TRIALS, Neonatal Herpes Simplex Virus Infection; and the ADVERSE REACTIONS sections of the labeling based on the results of Study 2.

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Andrew Gentles, PharmD, BCPS AQ-ID, Senior Regulatory Project Manager, at (240) 402-5708 or the mainline at (301) 796-1500.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, MD
Director
Division of Antiviral Product
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling
Prescribing Information

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEBRA B BIRNKRANT
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