NDA 208627/S-8
NDA 214518/S-3

SUPPLEMENT APPROVALS
POSTMARKETING COMMITMENT FULFILLED

SIGA Technologies, Inc.
Attention: Paul G. Long
Senior Director, Regulatory Affairs
4575 Research Way SW, Suite 110
Corvallis, Oregon 97333

Dear Paul Long:

Please refer to your supplemental new drug applications (sNDAs) dated and received December 6, 2023 for NDA 208627/S-8 and December 7, 2023 for NDA 214518/S-3 and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TPOXX (tecovirimat capsules) and TPOXX (tecovirimat) injection for intravenous use.

These Prior Approval sNDAs provide for the following changes to the Prescribing Information

- To update DRUG INTERACTIONS, 7.2 Effect of Other Drugs on TPOXX with phosphate binders information
- To update CLINICAL PHARMACOLOGY, 12.3 Pharmacokinetics with phosphate binders information.

APPROVAL & LABELING

We have completed our review of these applications, as amended. These are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS
Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, Instructions for Use, 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 *SPL Standard for Content of Labeling Technical Qs and As*.[2]

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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your applications, you are exempt from this requirement.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated December 6, 2023 containing the final report for the following postmarketing commitment listed in the July 13, 2018, approval letter for NDA 208627.

3417-5 Conduct an in vitro study to determine the potential for a drug interaction between tecovirimat and phosphate binders. If the results of the study are inconclusive or indicate binding of phosphate binders to tecovirimat is significant, conduct an in vivo study to determine the magnitude of interaction to inform the dosing regimen in patients who concomitantly take phosphate binders.

We have reviewed your submission and conclude that the above commitment was fulfilled.

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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, contact Raina Pandya, Regulatory Project Manager, at (240) 402-3941.

Sincerely,

{See appended electronic signature page}

Wendy Carter, DO
Director (Acting)
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

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/

WENDY W CARTER
06/03/2024 04:30:47 PM