CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214518Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	June 10, 2021
Application Type and Number:	NDA 214518
Product Name and Strength:	Tpoxx (tecovirimat) injection, 10 mg/mL
Total Product Strength:	200 mg/20 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Siga Technologies (SIGA)
PNR ID #:	2021-1044723946
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA Acting Division Director:	Lubna Merchant, MS, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Tpoxx, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. SIGA did not submited an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Tpoxx (tecovirimat) tablet was approved on July 13, 2018 under NDA 208627 for the treatment of human smallpox disease in adults and pediatric patients weighing 13 kg.

SIGA is pursuing an injection formulation for intraveneous administration in adult and pediatric patients (weighing 3 kg and up), therefore submitted the name, Tpoxx, for review under NDA 214518 on April 30, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 30, 2021.

Table 1. Relevant product information for Tpoxx Injection and Tpoxx (b) (4)[a]

	Tpoxx Injection	Tpoxx (b) (4)
Initial Approval Date	N/A	July 13, 2018
Intended Pronunciation	Tee-pahx or Te-Pox	
Active Ingredient	tecovirimat	
Indication	Tpoxx is indicated for the treatment of human smallpox disease in adults and pediatric patients.	
Dosage Form	(b) (4)	
Route of Administration		
Strength		

[a] Tpoxx Product information obtained at https: http://dailymed.nlm nih.gov/dailymed/drugInfo.cfm?setid=fce826ab-4d6a-4139-a2ee-a304a913a253 Accessed June 1, 2021.

Dose and Frequency	(b) (4)	
(How Supplied		
Storage		

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Tpoxx.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tpoxx would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Tpoxx.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Tpoxx.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[b].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their previous proprietary name submission (under approved NDA 208627) that the proposed name, Tpoxx, is derived from the virus, orthopoxvirus, which the product is indicated to treat. This proprietary name is comprised of a single word that has the abbreviation of 'po' (i.e. 'by mouth,orally'), in the prefix of the name. In this case, we find that the placement and presentation of the 'po' letter string is included in such a manner that it is unlikely to be misconstrued as a medical abbreviation, and thus would not be expected to pose a risk for medication errors. Thus, we conclude that the abbreviation 'po' in the proposed proprietary name is acceptable. There were no additional components of the name that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On May 26, 2021, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Tpoxx at the initial phase of the review.

2.2.4 Medication Error Data Selection of Cases

On June 1, 2021, we searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 for name confusion errors involving ***Tpoxx*** that would be relevant for this review.

Table 2. FAERS Search Strategy	
FAERS Field	Tpoxx
Initial FDA Receive Dates	August 1, 2018 – June 1, 2021

[b] USAN stem search conducted on May 10, 2021.

Product Name	Tpoxx
Verbatim Name(s)	n/a
Product Active Ingredient	tecovirimat
Drug Role	n/a
Event	Medication errors(narrow)
Country (derived)	USA

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, no reports related to this product were retrieved.

2.2.5 Safety Assessment of the Proposed Name, Tpoxx

The Applicant proposes a new dosage form, injection [200 mg/20 mL (10 mg/mL)], as a product line extension. The proposed formulation shares the same active ingredient as the approved Tpoxx tablet product (tecovirimat) and overlap in strength (200 mg versus 200 mg/20 mL). In addition, the products have an overlap in usual dose in patients of differing body weights (200 mg orally twice daily for a 13 kg to 25 kg patient versus 200 mg intravenously twice daily for a 40 kg patient), but differ in dosage form (tablet versus injection) and the route of administration (oral versus intravenous)(see Table 1 for more information). We also note that it is not unusual for a product line with multiple dosage forms to share one proprietary name. We considered whether these products sharing the same proprietary name, Tpoxx, may lead to medication errors. We note that because the products differ in dosage form and route of administration, a prescription order for Tpoxx will need to specify the dose and dosage form or route of administration on the prescribtion order. Thus, we determined that label and labeling mitigations may adequately address any residual risk of product confusion. In this specific case, we have determined that the different dosage forms can be managed under a single proprietary name. Therefore, we do not have concerns with the use of Tpoxx as the proprietary name for the proposed injection formulation.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Antivirals (DAV) via e-mail on June 7, 2021. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Antivirals (DAV) on June 7, 2021, they stated no additional concerns with the proposed proprietary name, Tpoxx.

3 CONCLUSION

The proposed proprietary name, Tpoxx, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO SIGA TECHNOLOGIES (SIGA)

We have completed our review of the proposed proprietary name, Tpoxx, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your submission, received on April 30, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [c]

[c] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

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/

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