CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216157Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

Date of This Review:	November 4, 2021
Application Type and Number:	NDA 216157
Product Name and Strength:	Oxbryta (voxelotor) tablet for oral suspension, 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Global Blood Therapeutics Inc. (GBT)
PNR ID #:	2021-1044724118
DMEPA 2 Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Oxbryta, 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. GBT did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Oxbryta (voxelotor) tablets, was approved on November 25, 2019 under NDA 213137 as a hemoglobin S polymerization inhibitor indicated for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. Oxbryta is currently marketed as a 500 mg tablet.

Global Blood Therapeutics now proposes NDA 216157 voxelotor tablets for oral suspension, 300 mg, for the proposed indication of (b) (4) treatment of sickle cell disease in adults and pediatric patients 4 years of age and older.

Thus, GBT submitted the name, Oxbryta, for the newly proposed dosage formulation (i.e. tablet for oral suspension) for review under NDA 216157 on August 13, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 13, 2021 for Oxbryta (voxelotor) tablets for oral suspension and the Prescribing Information for Oxbryta (voxelotor) tablets.

Table 1. Relevant Product Information for Velphoro (sucroferric oxyhydroxide)		
Product	**Oxbryta [Proposed] (NDA 216157)**	**Oxbryta [a] (NDA 213137)**
Initial Approval Date	Under review	November 25, 2019
Intended Pronunciation	ox-brye-ta	
Active Ingredient	voxelotor	
Indication	Treatment of sickle cell disease (SCD) in adults and pediatric patients 4 years of age and older.	Treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older.
Route of Administration	Oral	

[a] Oxbryta (voxelotor) [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2021 SEP 7. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/213137s000lbl.pdf

Dosage Form	Tablet for oral suspension	Tablets
Strength	300 mg	500 mg
Dose and Frequency§	• Adults and pediatric patients 12 years (b) (4) and older: 1,500 mg orally once daily. • Pediatric patients 4 to <12 years: Dosing with OXBRYTA is based on body weight. See Table 1 for complete dosing recommendations. (b) (4) <u>Recommended dosage for severe hepatic impairment (Child Pugh C):</u> • Adults and pediatric patients 12 years (b) (4) and older: 1,000 mg orally once daily. • Pediatric patients 4 to <12 years: Reduce the dose of OXBRYTA based on body weight. (b) (4) (b) (4)	1,500 mg orally once daily <u>Recommended dosage for severe hepatic impairment (Child Pugh C):</u> 1,000 mg once daily <u>Recommended dosage with strong CYP3A4 inhibitors or fluconazole:</u> 1,000 mg once daily <u>Recommended dosage with strong or moderate CYP3A4 inducers:</u> 2,500 mg once daily

<table>
<tr><td></td><td>(b) (4)</td><td></td></tr>
<tr><td>Instructions for Use</td><td>OXBRYTA 300 mg Tablets for Oral Suspension:
(b) (4)
<table><tr><th>Recommended Daily Dose</th><th>Number of Tablets for Oral Suspension</th><th>Minimum Recommended Volume of (b) (4)</th></tr><tr><td>300 mg</td><td>1</td><td>5 mL (1 teaspoon)</td></tr><tr><td>600 mg</td><td>2</td><td>10 mL (2 teaspoons)</td></tr><tr><td>900 mg</td><td>3</td><td>15 mL (3 teaspoons)</td></tr><tr><td>1200 mg</td><td>4</td><td>20 mL (4 teaspoons)</td></tr></table>• After the tablets start to disintegrate, swirl the contents of the cup until the tablets are (b) (4) dispersed, wait 1 to 5 minutes, swirl the contents of the cup again, and then
orally administer the contents of the cup.
• Resuspend any residue left in the cup in more (b) (4) clear drink and administer.
Repeat until no tablet residue is left in the cup.</td><td>For Oxbryta 500 mg Tablets:

Patients should swallow OXBRYTA tablets whole. Do not cut, crush, or chew the tablets.</td></tr>
<tr><td>How Supplied</td><td>•The 300 mg tablet for oral suspension is light yellow to yellow, round shaped, debossed with“300 D” on one side, and available in:
• Bottles of 60 tablets for oral suspension with a polyester coil and child-resistant closure:
NDC 72786-111-02
• Bottles of 90 tablets for oral suspension with a polyester coil and child-resistant closure:
NDC 72786-111-03</td><td>The 500 mg tablet is film-coated, light yellow to yellow, oval shaped, biconvex, debossed with “GBT 500” on one side, and available in:
• Bottles of 90 tablets with one desiccant canister, a polyester coil and child-resistant closure: NDC 72786-101-01</td></tr>
<tr><td>Storage</td><td>(b) (4)</td><td></td></tr>
</table>

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Oxbryta would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Non-Malignant Hematology (DNH) concurred with the findings of OPDP's assessment for Oxbryta.

2.2 SAFETY ASSESSMENT

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

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

GBT did not provide a derivation or intended meaning for the proposed proprietary name, Oxbryta, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On August 24, 2021, the Division of Non-Malignant Hematology (DNH) did not forward any comments or concerns relating to Oxbryta at the initial phase of the review.

2.2.4 Evaluation of a Single Proprietary Name for Multiple Dosage Forms

We note that the newly proposed tablets for oral suspension dosage formulation shares the same active ingredient as the currently approved Oxbryta tablets. It is a common and accepted practice to have a product line with multiple dosage forms managed under one proprietary name (e.g. Renvela and Pradaxa). Furthermore, we note that through our routine monitoring we have not identified any medication errors involving name confusion with the proprietary name Oxbryta. Therefore, given the precedence for using this naming convention, and the absence of any medication errors involving the proprietary name, we find the Sponsor's proposal to market the proposed product with the proprietary name Oxbryta acceptable. The difference in the product characteristics between the two dosage formulations for Oxbryta may be managed through labels and labeling.

2.2.5 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 2 communicated our findings to the Division of Non-Malignant Hematology (DNH). At that time we also requested additional information or concerns that could inform our review. The Division of Non-Malignant Hematology (DNH) did not express any additional concerns with the proposed proprietary name, Oxbryta.

[b] USAN stem search conducted on September 2, 2021.

3 CONCLUSION

The proposed proprietary name, Oxbryta, is acceptable.

If you have any questions or need clarifications, please contact Linda Wu, OSE project manager, at 240-402-5120.

3.1 COMMENTS TO GLOBAL BLOOD THERAPEUTICS INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 13, 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.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

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. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

***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.

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/

HINA S MEHTA
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CHI-MING TU
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