CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761238Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	6/29/2022
Responsible OND Division:	Division of Neurology 2 (DN 2)
Application Type and Number:	BLA 761238
Product Name and Strength:	Briumvi (ublituximab-xiiy) injection 150 mg/6 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	TG Therapeutics, Inc. (TG)
FDA Received Date:	October 25, 2021
Nexus NPNS ID #:	2021-57
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by TG for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761238.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On October 25, 2021, TG submitted a list of 8 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by TG:

Table 1. Suffixes submitted by TG***

(b) (4)	
2.	xiiy
(b) (4)	

We reviewed TG's proposed suffixes in the order of preference listed by TG using the principles described in the applicable guidance.[b]

2.1 ublituximab (b) (4)

TG's first proposed suffix, (b) (4)

[a] Request for Four-Letter Suffix BLA 761238. Raleigh (NC): TG Therapeutics, Inc.; 2021 Oct 25. Available from: \\CDSESUB1\evsprod\bla761238\0003\m1\us\ublituximab-4-letter-suffix-assessment-19oct2021.pdf

[b] Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

The proposed suffix -(b) (4) shares three identical letters in identical positions with the conditionally acceptable suffix (b) (4) *** for (b) (4) This similarity is supported by the FDA' s Phonetic and Orthographic Computer Analysis (POCA) system, which calculates an orthographic POCA score of 81%, indicating that the suffixes are orthographically highly similar. Thus, the proposed suffix (b) (4) is too similar to another nonproprietary name suffix that was received prior to the proposed nonproprietary name ublituximab-(b) (4) and that has been found to be conditionally acceptable by FDA. Therefore, we find the proposed suffix (b) (4) inconsistent with the principle outlined in section VI of the guidance[a] that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix (which we conclude reasonably includes previously received suffixes for products not yet licensed that are found conditionally acceptable).

2.2 ublituximab-xiiy

TG's second proposed suffix, -xiiy, is comprised of 3 distinct letters (x, i, y).

We determined that the proposed suffix -xiiy, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 2 ANALYSIS

These findings were shared with OPDP. On June 29, 2022, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Neurology 2 (DN 2) on June 29, 2022.

4 CONCLUSION

We find TG's proposed suffix -xiiy acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to ublituximab-xiiy. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendations for TG Therapeutics, Inc.

We find the nonproprietary name, ublituximab-xiiy, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, ublituximab-xiiy will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please

be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

We also note that the first proposed suffix is unacceptable for the following reason:

1. ublituximab-(b)(4)

   The proposed suffix, -(b)(4), is too similar to a previously-received proposed nonproprietary name suffix that has been found conditionally acceptable for a biological product that is under review by FDA. We find the proposed suffix, (b)(4), is therefore inconsistent with the principle outlined in section VI of the Nonproprietary Naming of Biological Products Guidance[a] that a suffix should not be too similar to any other FDA-designated nonproprietary name suffix (which we conclude reasonably includes previously received suffixes for products not yet licensed that are found conditionally acceptable).

[a] Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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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/

CARLOS M MENA-GRILLASCA
06/29/2022 05:15:41 PM

DANIELLE M HARRIS
07/01/2022 08:46:49 AM

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:	January 3, 2022
Application Type and Number:	BLA 761238
Product Name and Strength:	Briumvi (ublituximab-xxxx)[a] injection, 150 mg/6 mL (25 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	TG Therapeutics, Inc. (TG Therapeutics)
PNR ID #:	2021-1044724250
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Acting Team Leader:	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

[a] The nonproprietary name suffix has not been designated; therefore, the -xxxx is used throughout this review as placeholder.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Briumvi, 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. TG Therapeutics submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 25, 2021 and the draft prescribing information submitted on September 28, 2021.

- Intended Pronunciation: bree-UM-vee
- Nonproprietary Name: ublituximab-xxxx
- Indication of Use: Relapsing forms of multiple sclerosis, including clinically isolated syndrome (CIS) and relapsing-remitting multiple sclerosis (RRMS) in addition to active secondary progressive disease (SPMS)
- Route of Administration: Intravenous Infusion
- Dosage Form: Injection
- Strength: 150 mg/6 mL (25 mg/mL)
- Dose and Frequency: The recommended dosage is 150 mg starting dose (Day 1) then 450 mg on Day 15. Administer subsequent infusions (450 mg) every 6 months after the first infusion on Day 1.
- How Supplied: Supplied as 150 mg in 6 mL (25 mg/mL) single-dose vials in single-count cartons.
- Storage: This product should be stored refrigerated at 36°F to 46°F (2°C to 8°C) in original carton to protect from light. Do not freeze. Do not shake. (b) (4) Use the diluted solution immediately. If not used immediately, store for up to 24 hours at 2°C to 8°C (36°F to 46°F). (b) (4)
- Reference Listed Drug/Reference Product: N/A

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Briumvi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Briumvi.

2.2 SAFETY ASSESSMENT

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

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

TG Therapeutics did not provide a derivation or intended meaning for the proposed proprietary name, Briumvi, 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 December 15, 2021, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to Briumvi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-two practitioners participated in DMEPA's prescription studies for Briumvi. The responses did not directly overlap with any currently marketed products or any products in the pipeline.

However, two respondents in the voice study interpreted the proposed proprietary name as "Riamvi" which is a close hit to the currently marketed product, Riabni. We further evaluated the name pair, Briumvi and Riabni, and find that there are sufficient orthographic and phonetic between this name pair.

Orthographically, the names begin with different first letters (B vs. R). Additionally, Briumvi contains the rounded letter 'u' in the fourth position and contains no upstroke letters, whereas Riabni contains the upstroke letter 'b' in the fourth position which gives the names different shapes when scripted.

Phonetically, the second syllables (UM vs. AB) and the onset of the third syllables (vee vs. nee) sound different when spoken.

Additionally, FDA's Phonetic and Orthographic Computer Analysis (POCA) program calculates a combined score of 52% for this name pair suggesting there is low similarity between the names.

When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is minimal (see Appendix F).

Additionally, 11 respondents in the voice study omitted the beginning letter sound 'B'.

Appendix B contains the results from the prescription simulation studies.

[b] USAN stem search conducted on October 26, 2021.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 45 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

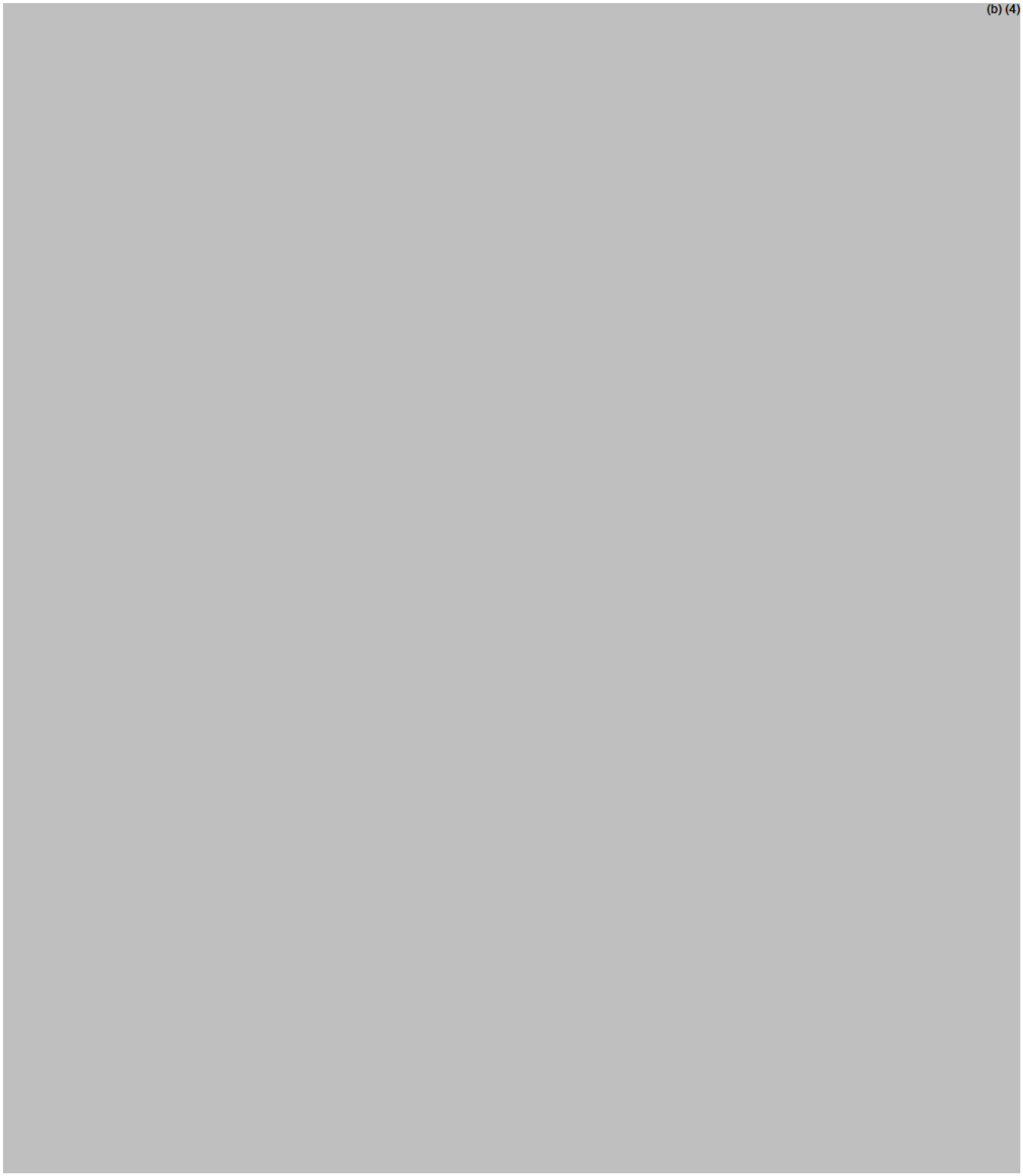
Table 1 lists the number of names retrieved from our POCA search, FDA Prescription Simulation Study and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	39
Low similarity name pair: combined match percentage score ≤54%	11

(b) (4)

[c] POCA search conducted on October 26, 2021 in version 4.4.



2.2.8 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 51 names contained in Table 1 determined none of the names will pose a risk for confusion with Briumvi as described in Appendices C through H.

2.2.9 Communication of DMEPA's Determination

On January 3, 2022, DMEPA 2 communicated our determination to the Division of Neurology 2 (DN 2).

3 CONCLUSION

The proposed proprietary name, Briumvi, is acceptable.

If you have any questions or need clarifications, please contact Lopa Thambi OSE project manager, at 301-796-5354.

3.1 COMMENTS TO TG THERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on October 25, 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. [d]

[d] 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.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

[e] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

c. FDA Prescription Simulation Studies: DMEPA staff also conducts a prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. 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.

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

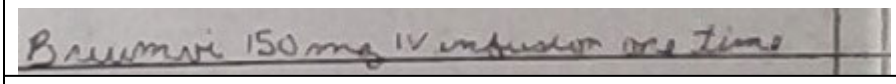
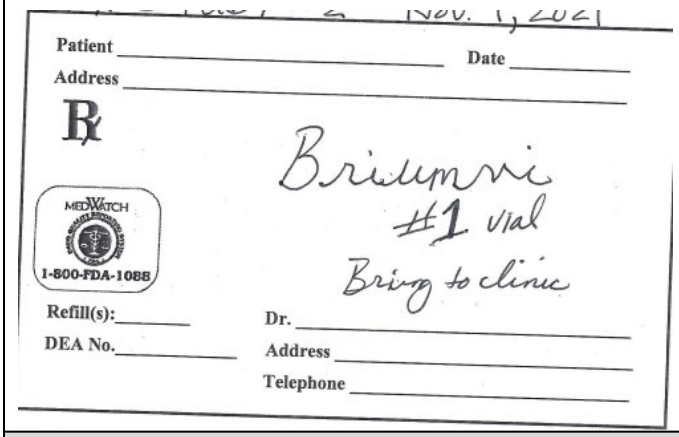
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Briumvi Study (Conducted on November 10, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Briumvi Bring to clinic #1 vial
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Briumvi	

FDA Prescription Simulation Responses (Aggregate Report)

263 People Received Study
92 People Responded

Study Name: Briumvi

Total	21	20	23	28	92
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
BREEMVI	0	0	1	0	1
BREUMVI	0	0	1	1	2
BREUMVY	0	0	2	0	2
BRILEMVI	1	0	0	0	1
BRILIMVI	1	0	0	0	1
BRIOMVI	0	0	1	0	1

BRIUMVI	17	20	5	8	50
BRIUMVRI	1	0	0	0	1
BRIUMVY	0	0	2	0	2
BRIUMYI	1	0	0	0	1
BRUIMVI	0	0	0	6	6
BRUMRI	0	0	0	1	1
BRUMRIC	0	0	0	1	1
BRUMVI	0	0	0	9	9
BRUMVI 150MG	0	0	0	1	1
BRUUMVI	0	0	0	1	1
RAYUMVY	0	0	1	0	1
REIUMVI	0	0	1	0	1
REMVY	0	0	1	0	1
REUMVI	0	0	1	0	1
REUMVY	0	0	1	0	1
RIAMVI	0	0	2	0	2
RIUMVI	0	0	3	0	3
RIUMVY	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Briumvi	100%	Proposed proprietary name that is the subject of this review.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Barium	69

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Librium	65	This name pair has sufficient orthographic and phonetic differences. Orthographically, the names begin with different first letters (B vs. L). Additionally, we acknowledge that both contain the letter string ‘brium’, however it appears in different positions of each name (prefix ‘bri’ /infix ‘um’ vs. infix ‘bri’ /suffix ‘um’)

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			which gives the names different shapes when scripted. Phonetically, the first syllables (bree vs. lib), second syllables (um vs. ri) and third syllables (vee vs. um) sound different when spoken. Additionally, Briumvi is available in one strength (150 mg/6 mL (25 mg/mL)), whereas Librium is available in three strengths (5mg, 10 mg and 25 mg) which must be specified on the prescription. Furthermore, the following product characteristics may provide additionally differentiation if included: there is no direct overlap in dosage form (injection vs. capsule), frequency of administration (on day 1, on day 15 and then every 6 months after the first infusion on day 1 vs. three or four times daily) or route of administration (intravenous infusion vs. oral). Lastly, Librium is a controlled substance (CIV) and must include the product strength, directions for use and quantity to dispense on a prescription.[f] When all of the aforementioned mitigations are considered in totality,

[f] Code of Federal Regulations. 21CFR Part 1306.05(a)

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			we find the risk of name confusion is minimal.
2.	(b) (4)***	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the lengths of the names (7 letters vs. 9 letters) are dissimilar when scripted. Additionally, Briumvi contains the dotted letter 'i' at the end of the suffix, whereas (b) (4)*** contains a (b) (4) which is not present in Briumvi which gives the names different shapes when scripted. Phonetically, the second syllables (UM vs. (b) (4)) and rimes of the third syllables (/ee/ vs. (b) (4)) sound different when spoken.
3.	Brineura	60	This name pair has sufficient orthographic and phonetic differences. The following product characteristics may provide additional differentiation if included: there is no direct overlap in dose and frequency of administration (150 mg on day 1, 450 mg on day 15 and then 450 mg every 6 months after the first infusion on day 1 vs. 300 mg fixed dose followed by an infusion of flushing solution, every 2 weeks) or route of administration (intravenous infusion vs. intraventricular infusion). Additionally, Brineura is administered

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			into the cerebrospinal fluid (CSF) by infusion via a surgically implanted reservoir and catheter (intraventricular access device) and it is recommended that the first dose be administered at least 5 to 7 days after device implantation. Furthermore, Brineura would be administered by, or under the direction of, a physician experienced in intraventricular administration. These differences in product characteristics can minimize the risk for confusion between the products.
4.	Triumeq	60	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.
6.	Brioschi	59	This name pair has sufficient orthographic and phonetic differences.
7.	Breyanzi	58	This name pair has sufficient orthographic and phonetic differences. Phonetically, offset of the first syllable (bree vs. braye), second syllables (UM vs. an') and the onset of the third syllables (zee vs. vee) sound different when spoken. Furthermore, the following product characteristics may provide additional differentiation if included: there is no direct overlap in dose and frequency of administration (150 mg on day 1, 450 mg on day 15 and then 450 mg every 6 months after the first infusion on day 1

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			vs. single dose containing a target of 100×10^6 CAR-positive viable T cells two to seven days after completion of lymphodepleting chemotherapy) or route of administration (intravenous infusion vs. subcutaneous). Additionally, Breyanzi is unlikely to be dispensed from a pharmacy as it is patient-specific Chimeric Antigen Receptor (CAR) T cell product that consists of two individually formulated CD4+CAR+ and CD8+CAR+ frozen T cell suspensions prepared in patient-specific 5 mL infusion vials stored frozen (-130˚ C). It is shipped in liquid nitrogen to be administered by trained qualified personal. A patient's name and identifier will be on each dose because patients receiving Breyanzi undergo leukapheresis to enable patient-specific product generation. These differences in product characteristics can minimize the risk for confusion between the products.
8.	Brilinta	58	This name pair has sufficient orthographic and phonetic differences. Orthographically, the upstroke letter 'l' and cross-stroke letter 't' in Brilinta which is not present in Briumvi gives the names different shapes when scripted.

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, the second syllables (UM vs. lin) and third syllables (vee vs. tah) sound different when spoken. Additionally, Briumvi is available in one strength (150 mg/6 mL (25 mg/mL)), whereas Brilinta is available in two strengths (60 mg and 90 mg) which must be specified on the prescription and there is no direct overlap in strength. Furthermore, the following product characteristics may provide additionally differentiation if included: there is no direct overlap in dose and frequency of administration (150 mg on day 1, 450 mg on day 15, then 450 mg every 6 months after the first infusion on day 1 vs. 180 mg loading dose then/or 60 mg or 90 mg twice daily), dosage form (injection vs. tablet), or route of administration (intravenous infusion vs. oral).
9.	Brukinsa	58	This name pair has sufficient orthographic and phonetic differences.
10.	Baridium	56	This name pair has sufficient orthographic and phonetic differences. Orthographically, Baridium contains the letter ‘a’ in the prefix between the letters “B” and ‘r’ which is not present in Briumvi which may provide some differentiation. Additionally, Briumvi does not contain any upstroke letters, whereas Baridium contains the upstroke letter ‘d’ in the infix which

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			give the names different shapes when scripted. Lastly, we acknowledge that both contain the letter string 'um', however it appears in different positions (infix vs. suffix) which provides additional differentiation. Furthermore, the following product characteristics may provide additional differentiation if included: there is no direct overlap in strength (150 mg/6 mL (25 mg/mL) vs. 97.2 mg), dose and frequency of administration (150 mg on day 1, 450 mg on day 15, then 450 mg every 6 months after the first infusion on day 1 vs. 1 or 2 tablets 3 times per day as needed), dosage form (injection vs. tablet) or route of administration (intravenous infusion vs. oral).
11.	Besremi	56	This name pair has sufficient orthographic and phonetic differences.
12.	Breztri	56	This name pair has sufficient orthographic and phonetic differences.
13.	Bromday	56	This name pair has sufficient orthographic and phonetic differences.
14.	Briviact	54	This name pair has sufficient orthographic and phonetic differences. Orthographically, the ending of the infixes (m vs. i) and the suffixes (vi vs. act) look sufficiently different when scripted.

No.	**Proposed name:** Briumvi **Established name:** ublituximab-xxxx **Dosage form:** Injection **Strength(s):** 150 mg/6 mL (25 mg/mL) **Usual Dose:** The recommended dosage is 150 mg on Day 1, 450 mg on Day 15 and 450 mg every 6 months after the first infusion on Day 1.	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, the second syllables (UM vs. VEE) and the third syllables (vee vs. act) sound different when spoken.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)
1.	Imbruvica	54
2.	Viridium	52
3.	Riabni	52
4.	Biktarvy	50
5.	Erbium	50
6.	Rubidium	50
7.	82 Rubidium	50
8.	Brovana	48
9.	Breo Ellipta	36
10.	Plegridy	30

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	66	Proposed proprietary name for IND 126779 found unacceptable by DMEPA (OSE# 2017-13946987 dated September 8, 2017). NDA 209355 approved under proprietary name, Bryhali.
2.	Triumph	66	Veterinary drug product.
3.	Nobrium	63	International product formerly marketed in Ireland, Italy, Netherlands, Spain, Switzerland, United Kingdom, and Hungary.

No.	Name	POCA Score (%)	Failure preventions
4.	(b) (4)***	62	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) dated February 9, 2017). (b) (4)*** found conditionally acceptable on August 4, 2020 (OSE# (b) (4)) for IND (b) (4).
5.	Protium I.V	60	International product marketed in Ireland and the United Kingdom.
6.	Bromfed	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Brondil	58	International product marketed in the Philippines and formerly marketed in Thailand.
8.	Bromdec	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	Terbium	56	Product is not a drug. It is a chemical element (Tb).
10.	Menrium 10-4	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
11.	Menrium 5-4	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Menrium 5-2	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[g].

No.	Name	POCA Score (%)
1.	Primlev	61
2.	Tri-Mili	60
3.	Tri-Luma	59
4.	Prinivil	58
5.	Dr. Numb	56
6.	Triavil	56
7.	Triavil 2-10	56
8.	Triavil 2-25	56
9.	Triavil 4-10	56
10.	Triavil 4-25	56
11.	Triavil 4-50	56
12.	Tru-Micin	56

[g] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

No.	Name	POCA Score (%)
13.	Varubi	55

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/s/

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