CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761232Orig1s000

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:	3/17/2022
Responsible OND Division:	Division of Oncology 2 (DO2) for IND 126875
	Division of Oncology 3 (DO3) for BLA 761232
Application Type and Number:	IND 126875
	BLA 761232
Product Name and Strength:	Tevimbra (tislelizumab-jsgr) injection
	100 mg/10 mL (10 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	BeiGene USA, Inc (BeiGene)
FDA Received Date:	July 12, 2021
Nexus NPNS ID #:	2021-78 (IND)
	2021-39 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Division Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by BeiGene for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761232.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On May 28, 2021 (IND) and July 12, 2021 (BLA), BeiGene submitted a list of 10 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 BeiGene:

Table 1. Suffixes submitted by BeiGene***

1.	jsgr
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

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

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[a] Proprietary Name and Nonproprietary Name BLA 761232. San Mateo (CA): BeiGene USA, Inc; 2021 Jul 12. Available from: \\CDSESUB1\evsprod\bla761232\0001\m1\us\proprietary-name.pdf

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

2.1 tislelizumab-jsgr

BeiGene's first proposed suffix, -jsgr, is comprise of 4 distinct letters.

We determined that the proposed suffix -jsgr, 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 March 15, 2022, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 2 (DO2) and Division of Oncology 3 (DO3) on March 15, 2022.

4 CONCLUSION

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

4.1 Recommendations for BeiGene USA, Inc

We find the nonproprietary name, tislelizumab-jsgr, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, tislelizumab-jsgr 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 finding.

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
03/17/2022 11:39:02 AM

DANIELLE M HARRIS
03/18/2022 01:38:33 PM

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)

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Date of This Review:	February 3, 2022
Application Type and Number:	IND 126875 & BLA 761232
Product Name and Strength:	Tevimbra (tislelizumab-xxxx[a]) injection, 100 mg/10 mL (10 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	BeiGene USA, Inc. (BeiGene)
PNR ID #:	2021-1044724284 & 2021-1044724282
DMEPA 2 Safety Evaluator:	Sarah Thomas, PharmD
DMEPA 2 Team Leader:	Janine Stewart, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a]Since the proper name for Tevimbra has not yet been determined, "tislelizumab-xxxx" is used throughout this review as the nonproprietary name for this product.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

BeiGene previously submitted the proposed proprietary name, [(b) (4)]***, under IND 126875 on February 5, 2020. [(b) (4)]*** was found conditionally acceptable by DMEPA on June 24, 2020[b]. Because BeiGene submitted a new proprietary name review for [(b) (4)]*** under INDs 126875, [(b) (4)] and 135699 on May 28, 2021, BeiGene was advised to withdraw the conditionally acceptable name, [(b) (4)]*** under IND 126875. Their proprietary name withdrawal was received on June 4, 2021.

On May 28, 2021 BeiGene submitted a request for proprietary name for [(b) (4)]*** under INDs 126875, 135699, and [(b) (4)] On June 2, 2021 BeiGene submitted a request for proprietary name review for [(b) (4)]*** under INDs [(b) (4)] Last, on July 12, 2021, BeiGene submitted a request for proprietary name review for [(b) (4)]*** under BLA 761232. However, we found the name, [(b) (4)]*** unacceptable due to [(b) (4)] ***, under BLA 761232, IND 126875, IND [(b) (4)], IND 135699, IND [(b) (4)], and IND [(b) (4)] on October 7, 2021.[c]

Thus, BeiGene submitted the name, Tevimbra, for review on November 12, 2021 under BLA 761232 and under IND 126875. Of note, Tevimbra was found conditionally acceptable for spartalizumab under IND [(b) (4)] on October 24, 2019.[d] BeiGene was advised to withdraw the conditionally acceptable name, Tevimbra*** under IND [(b) (4)], and their proprietary name withdrawal was received on December 14, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 12, 2021 and amendment received on December 28, 2021.

- Intended Pronunciation: Teh-vim'-brah
- Nonproprietary Name: tislelizumab-xxxx

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[b] Straka, M. Proprietary Name Review for [(b) (4)]*** (IND 126875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUN 24. RCM No.: 2020-37677109.

[c] Mahmoud, S. Proprietary Name Review for [(b) (4)]*** (BLA 761232, IND 126875, IND [(b) (4)], IND 135699, IND [(b) (4)], and IND [(b) (4)]. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 OCT 7. RCM No.: 2021-1044724055; 2021-1044723998; 2021-1044723997; 2021-1044724000; 2021-1044724004; 2021-1044724003.

[d] Stewart, J. Proprietary Name Review for [(b) (4)] (IND [(b) (4)]). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 OCT 24. PNR ID No. 2019-31338732.

- Indication of Use: Treatment of patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma after prior systemic therapy
- Route of Administration: intravenous
- Dosage Form: injection
- Strength: 100 mg/10 mL (10 mg/mL)
- Dose and Frequency: 200 mg intravenously every 3 weeks
- How Supplied: single-dose vial with rubber stopper and an aluminum cap packaged in a carton
- Storage: Store in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze. Do not shake.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tevimbra would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2), the Division of Oncology 2 (DO2), and the Division of Oncology 3 (DO3) concurred with the findings of OPDP's assessment for Tevimbra.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

BeiGene did not provide a derivation or intended meaning for the proposed proprietary name, Tevimbra, in their submission. This proprietary name is comprised of a single word that contains the letters 'im', which is the abbreviation for the intramuscular route of administration. Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of this abbreviation in the middle of the name and the lack of prominence of this abbreviation makes it unlikely that the letters 'im' within the proposed proprietary name, Tevimbra, could lead to confusion in this case.

[e] USAN stem search conducted on December 8, 2021.

2.2.3 Comments from Other Review Disciplines at Initial Review

On November 29, 2021 and December 8, 2021, the Division of Oncology 3 (DO3) and the Division of Oncology 2 (DO2) did not forward any comments or concerns relating to Tevimbra at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One-hundred and four practitioners participated in DMEPA's prescription studies for Tevimbra. One respondent in the Computerized Physician Order Entry (CPOE) study selected atomoxetine instead of Tevimbra from the picklist. Upon further evaluation, we note that the participant typed "tomo" of instead of "tevi", and as a result their picklist did not include Tevimbra; thus, they selected Atomoxetine from the picklist. In addition, the respondent reported in the comment field that "clicked out and can't go back to see the drug. randomly selected since I have to pick one to proceed." We further evaluated the name pair, Tevimbra and Atomoxetine, and find that there is low phonetic and orthographic similarity (see Appendix F). This is supported by the FDA's Phonetic and Orthographic Computer Analysis (POCA) program[f], which calculates a combined score of 26%, suggesting there is low similarity between these names. As such, we find the risk of name confusion minimal.

The other responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[g] identified 76 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 and the FDA Prescription Simulation 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%	68

[f] POCA search conducted on December 20, 2021 in version 4.4.

[g] POCA search conducted on December 8, 2021 in version 4.4.

Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 77 names contained in Table 1 determined none of the names will pose a risk for confusion with Tevimbra as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

On February 3, 2022, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2) and the Division of Oncology 3 (DO3).

3 CONCLUSION

The proposed proprietary name, Tevimbra, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO BEIGENE USA, INC.

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

If any of the proposed product characteristics as stated in your submission received on November 12, 2021 and amendment received on December 28, 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. [h]

[h] 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[i]. 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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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.

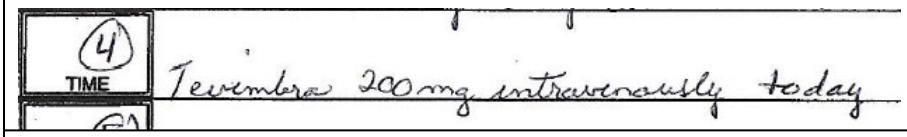
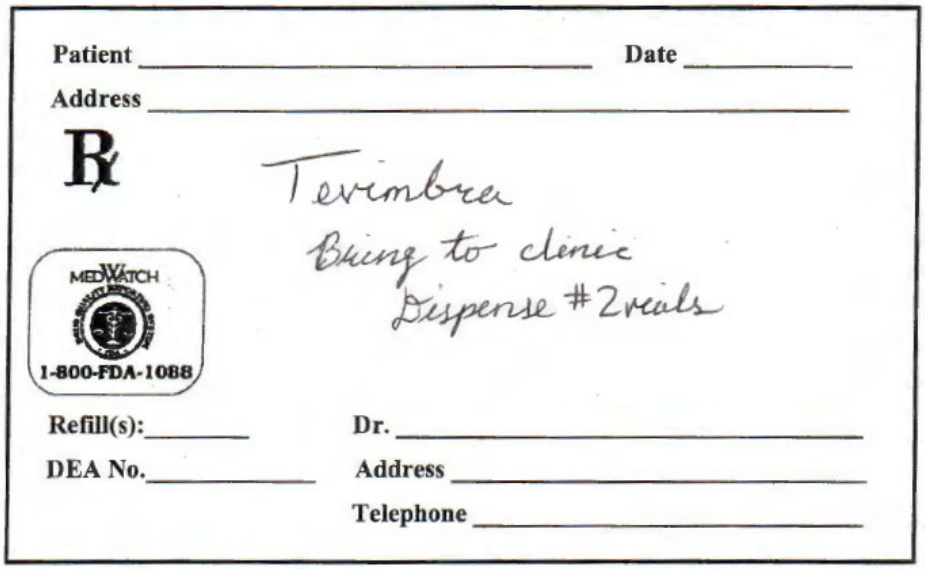
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Tevimbra Study (Conducted on December 3, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Tevimbra Bring to clinic Dispense two vials
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Tevimbra	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Tevimbra

As of Date 12/20/2021

262 People Received Study

104 People Responded

Study Name: Tevimbra

Total	24	26	21	33	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
ATOMOXETINE	0	1	0	0	1
TAVIMBRA	0	0	3	0	3
TEIMBRA	1	0	0	0	1
TETHIMBRA	0	0	1	0	1
TEUIMBRA	0	0	0	1	1
TEVEMBRA	0	0	0	1	1
TEVIBRU	0	0	0	1	1
TEVIMBERA	0	0	0	3	3
TEVIMBRA	22	25	6	23	76
TEVIMBRA 200 MG	0	0	0	1	1
TEVIMBRE	1	0	0	0	1
TEVIMBRO	0	0	0	2	2
TEVIMDERA	0	0	0	1	1
TIMBRIMBRA	0	0	1	0	1
TIMVEMBRA	0	0	1	0	1
TINFIMBRA	0	0	1	0	1
TIVAMBURA	0	0	1	0	1
TIVIMBRA	0	0	6	0	6
TUDIMBRA	0	0	1	0	1

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

No.	**Proposed name:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	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.	Tevimbra	100	Proposed proprietary name 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.	Vizimpro	65
2.	Tecfidera	59
3.	Imdevimab	58
4.	Tecentriq	56
5.	Limbrel	55

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:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	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.	Tempra	68	This name pair has sufficient orthographic and phonetic differences.
2.	Tempra 1	68	This name pair has sufficient orthographic and phonetic differences.
3.	Tempra 3	68	This name pair has sufficient orthographic and phonetic differences.
4.	Myfembree	66	This name pair has sufficient orthographic and phonetic differences.
5.	Trazimera	65	This name pair has sufficient orthographic and phonetic differences.
6.	Levitra	64	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	**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**
7.	Tuzistra	61	The infixes of the Tevimbra and Tuzistra XR name pair (-vim- versus -zis-) provide some orthographic differentiation. The second (vim' versus zis) and third (brah versus tra) syllables of this name pair sound different. In addition, the modifier "XR" in Tuzistra XR will provide some differentiation if included on a prescription for Tuzistra XR. Although Tevimbra and Tuzistra XR are both single strength products [100 mg/10 mL (10 mg/mL) versus 14.7 mg codeine and 2.8 mg chlorpheniramine per 5 mL] where the strength may be omitted on a prescription, the name pair differs in dose (200 mg versus 10 mL or 29.4 mg codeine and 5.6 mg chlorpheniramine). Also, this name pair differs in dosage form (injection versus extended-release oral suspension), route of administration (intravenous versus oral), and frequency of administration (every 3 weeks versus every 12 hours as needed). Additionally, injectable oncology drugs typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the difference in dosage form, route of administration, dose, and frequency of administration is minimized.

No.	**Proposed name:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	**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**
8.	Servira	60	This name pair has sufficient orthographic and phonetic differences.
9.	Tosymra	60	This name pair has sufficient orthographic differences. The second syllables (vim' versus SIM) and third syllables (brah versus ruh) sound different. Although Tevimbra and Tosymra share similarity in strength and are both single strength products [100 mg/10 mL (10 mg/mL) versus 10 mg] where the strength may be omitted on a prescription, the name pair differs in dose (200 mg versus 10 mg or 1 spray). Also, this name pair differs in dosage form (injection versus nasal spray), route of administration (intravenous versus intranasal), and frequency of administration (every 3 weeks versus once or once per hour for 3 doses). Additionally, injectable oncology drugs typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the difference in dosage form, route of administration, dose, and frequency of administration is minimized.
10.	Tresiba	60	This name pair has sufficient orthographic and phonetic differences.
11.	Zembrace	60	Zembrace is the root name for Zembrace Symtouch. Tevimbra and the root name Zembrace, and Tevimbra and Zembrace Symtouch

No.	**Proposed name:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	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**
			name pairs have sufficient orthographic and phonetic differences.
12.	Etesevimab	59	This name pair has sufficient orthographic and phonetic differences.
13.	Actemra	58	This name pair has sufficient orthographic and phonetic differences.
14.	Hemlibra	58	This name pair has sufficient orthographic and phonetic differences.
15.	Tembexa	58	This name pair has sufficient orthographic and phonetic differences.
16.	Trumenba	58	The prefixes (Te versus Tru) and infixes (-vim- versus -men-) provide some orthographic differentiation. The first syllables (Teh versus Tru) and second syllables (vim' versus men) sound different. Although Tevimbra and Trumenba are both single strength products [100 mg/10 mL (10 mg/mL) versus 120 mcg/0.5 mL] where the strength may be omitted on a prescription, the name pair differs in dose (200 mg versus 0.5 mL). Also, this name pair differs in dosage form (injection versus suspension for intramuscular injection), route of administration (intravenous versus intramuscular), and frequency of administration (every 3 weeks versus at 0 and 6 months or at 0, 1–2, and 6 months). Additionally, injectable oncology drugs typically undergo independent double checks by 2 pharmacists in the usual clinical setting. The likelihood of both pharmacists overlooking the

No.	**Proposed name:** Tevimbra **Established name:** tislelizumab-xxxx **Dosage form:** injection **Strength(s):** 100 mg/10 mL (10 mg/mL) **Usual Dose:** 200 mg intravenously every 3 weeks	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**
			difference in dosage form, route of administration, dose, and frequency of administration is minimized.
17.	Tysabri	58	This name pair has sufficient orthographic and phonetic differences.
18.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
19.	Tribenzor	56	This name pair has sufficient orthographic and phonetic differences.
20.	Trivora	56	This name pair has sufficient orthographic and phonetic differences.
21.	Trivora-28	56	This name pair has sufficient orthographic and phonetic differences.
22.	Tremfya	55	This name pair has sufficient orthographic and phonetic differences.
23.	Typhim Vi	55	This name pair has sufficient orthographic and phonetic differences.
24.	Depandro 100	52	This name pair has sufficient orthographic and phonetic differences.
25.	Emtriva	52	This name pair has sufficient orthographic and phonetic differences.
26.	Tecovirimat	51	This name pair has sufficient orthographic and phonetic differences.
27.	Atelvia	50	This name pair has sufficient orthographic and phonetic differences.
28.	Vibra-Tabs	50	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Atomoxetine	26

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.	Semintra	68	Veterinary product per DailyMed database.
2.	Tempra 2	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	(b) (4) ***	64	Proposed proprietary name for IND 116647 found unacceptable by DMEPA (Panorama #2017-15207175 dated August 16, 2017). BLA 761090 approved under proprietary name Takhzyro.
4.	(b) (4) ***	63	Proposed proprietary name for ANDA 091193 was found conditionally acceptable by DMEPA (OSE # 2012-222 dated June 13, 2012). However, ANDA 091193 received a Complete Response (CR) action on April 25, 2013 and October 3, 2014. Subsequently, ANDA 091193 was approved on May 3, 2016 under the established name 'baclofen', under which the product is currently marketed.
5.	(b) (4) ***	61	Proposed proprietary name for (b) (4)
6.	Tavist Da	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Teramine Er	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
8.	(b) (4) ***	58	Proposed proprietary name for NDA 21926 was found unacceptable by DMEPA on November 9, 2005 (OSE# 05-0296) and April 3, 2007 (OSE# 2007-610). NDA 21926 was approved under the proprietary name, Treximet.
9.	(b) (4) ***	57	Proposed proprietary name for (b) (4)

No.	Name	POCA Score (%)	Failure preventions
10.	Etofibrate	56	Etofibrate is the established name for an international product marketed in Spain, Chile, Austria, Portugal, Germany, Hong Kong, Malaysia, Singapore Switzerland, Brazil, and Mexico.
11.	Tebamide	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	(b) (4) ***	56	Proposed proprietary name for (b) (4)
13.	Trivora-21	56	Brand discontinued with no TE codes provided per Drugs@FDA database.
14.	Tymtran	56	Brand discontinued with no generic equivalents available. NDA 018296 withdrawn FR effective 03/02/1994.
15.	Veteribac	52	Veterinary product.
16.	Emerita	47	Family name for an over-the-counter natural women's wellness product line (e.g. feminine hygiene, midlife balance, intimacy, skin care, health supplements, and lubricants). Therefore, a prescription must include additional information to indicate the appropriate product.

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	67
2.	Ixempra	64
3.	Cresemba	61
4.	Kesimpta	60
5.	Pimtrea	60
6.	Stendra	60
7.	Hizentra	59
8.	(b) (4) ***	59

[j] 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 (%)
9.	Selfemra	59
10.	Peramivir	58
11.	(b) (4)***	58
12.	(b) (4)***	58
13.	Adizem-Sr	57
14.	Bicitra	57
15.	Cotempla	57
16.	(b) (4)***	57
17.	Belsomra	56
18.	Kcentra	56
19.	(b) (4)***	56
20.	(b) (4) **	56
21.	Zinbryta	56
22.	Primperan	55
23.	Vitamin B 12	55
24.	Vitamin B12	55
25.	Vitamin B6	55
26.	Vitamin B9	55

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