CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761354Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	December 21, 2022
Application Type and Number:	BLA 761354
Product Name and Strength:	Tofidence (tocilizumab-xxxx)[a] injection 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Biogen MA Inc. (Biogen)
PNR ID #:	2022-1044724789
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia Rychlik, Pharm.D.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, Pharm.D.

[a]The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "tocilizumab-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Tofidence, 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. Biogen 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 4, 2022.

- Intended Pronunciation: toe fye' dens
- Nonproprietary Name: tocilizumab-xxxx
- Indication of Use:

  Rheumatoid Arthritis (RA): Adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

  Polyarticular Juvenile Idiopathic Arthritis (PJIA): Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis.

  Systemic Juvenile Idiopathic Arthritis (SJIA): Patients 2 years of age and older with active systemic juvenile idiopathic arthritis.
- Route of Administration: intravenous infusion
- Dosage Form: injection
- Strength: 80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), and 400 mg/20 mL (20 mg/mL)
- Dose and Frequency:
  Rheumatoid Arthritis (RA):
  Recommended Adult Intravenous Dosage: When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response.
  Polyarticular Juvenile Idiopathic Arthritis (PJIA):
  Recommended Intravenous PJIA Dosage Every 4 Weeks
  Patients less than 30 kg weight-10 mg per kg
  Patients at or above 30 kg weight-8 mg per kg
  Systemic Juvenile Idiopathic Arthritis:
  Recommended Intravenous SJIA Dosage Every 2 Weeks
  Patients less than 30 kg weight-12 mg per kg
  Patients at or above 30 kg weight-8 mg per kg
- How Supplied: single-dose vials as a preservative-free concentrate (20 mg/mL) solution for intravenous infusion.

- Storage: Tofidence must be refrigerated at 36°F to 46°F (2ºC to 8ºC). Do not freeze. Protect the vials from light by storage in the original package until time of use.
- Reference Product: Actemra (BLA 125276)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tofidence would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Tofidence. The Division of Rheumatology and Transplant Medicine (DRTM) expressed the following concerns:

- "As a consumer, I think "Tofidence" is rather close to "confidence". As per Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products (Dec 2020)— "In determining whether a name is misleading, common morphological and semantic associations are considered along with phonesthemes (the sound of the name) and phono-semantics (meaning conveyed by the sound of the word) of the name. Research has shown that linguistic characteristics can influence the way people perceive a product, particularly when it is new and unfamiliar as is the case with newly proposed proprietary names."
- "I don't have "Tofidence" in this name".
- "I have concerns with this name choice. The selected name Tofidence sounds like the word "confidence" which may imply or overstate the efficacy or imply unique effectiveness and may be potentially misleading."

We shared DRTM's comments with the Office of Prescription Drug Promotion (OPDP) and they maintain their non-objection to the proposed proprietary name based on the rationale below:

OPDP has reevaluated the proposed proprietary name Tofidence given OND's request for reassessment from a promotional perspective. OPDP maintains their non-objection to "Tofidence" from a promotional perspective. The proposed indication is for the treatment of rheumatoid arthritis in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. The OPDP PNR team discussed that the proposed proprietary name could potentially evoke "confidence," which can be defined as "faith or belief that one will act in a right, proper, or effective way" (https://www.merriam-webster.com/dictionary/confidence; accessed 11/16/2022). FDA approval of this drug would mean that it was demonstrated to be safe and effective for the intended use. Hence, the team concluded that if the word "confidence" is evoked, it would not be false or misleading from a promotional perspective because the drug would have demonstrated effectiveness for its intended use and be expected to "act in [an]…effective way. Therefore, they have determined that the proposed name is not false or misleading from a promotional perspective. Thus, we requested that OPDP reassess the name.

DMEPA communicated OPDP's reassessment and non-objection to the name to the review team via e-mail on November 21, 2022. We also stated that based on OPDP's input and past input from the FDA Office of the Chief Counsel (OCC) regarding objecting to a proposed proprietary name based on promotional, misleading or misbranding aspects, we have determined we lack the basis to find this name unacceptable for misbranding reasons. The review team did not forward any additional concerns related to the name.

2.2 SAFETY ASSESSMENT

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

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

Biogen did not provide a derivation or intended meaning for the proposed proprietary name, Tofidence in their submission. This proprietary name is comprised of a single word. We note that Tofidence contains the letter string '-id-,' a medical abbreviation for "intradermal". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviation, '-id-,' in the infix of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, in this case, we do not object to the inclusion of the letter string, '-id', in the infix of the proposed proprietary name.

2.2.3 Comments from Other Review Disciplines at Initial Review

On October 31, 2022, the Division of Rheumatology and Transplant Medicine (DRTM) raised concerns relating to Tofidence at the initial phase of the review (see Section 2.1 above).

2.2.4 FDA Name Simulation Studies

Ninety-four (n=94) practitioners participated in DMEPA's prescription studies for Tofidence. The 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[c] identified 216 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.

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[b] USAN stem search conducted on October 7, 2022.

[c] POCA search conducted on October 7, 2022 in version 5.0

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 (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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	191
Low similarity name pair: combined match percentage score ≤54%	24

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

Our analysis of the 218 names contained in Table 1 determined none of the names will pose a risk for confusion with Tofidence as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On December 20, 2022, DMEPA 1 communicated our determination to the Division of Rheumatology and Transplant Medicine (DRTM).

3 CONCLUSION

The proposed proprietary name, Tofidence, is conditionally acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO BIOGEN MA INC.

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

If any of the proposed product characteristics as stated in your submission, received on October 4, 2022, 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 names7F[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

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

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.

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.

   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.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
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 <u>with</u> overlapping or similar strengths or doses.

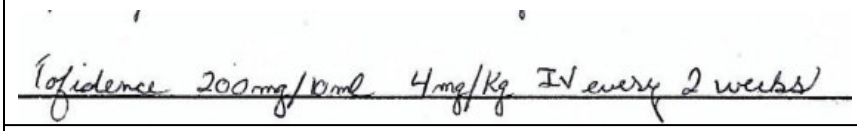
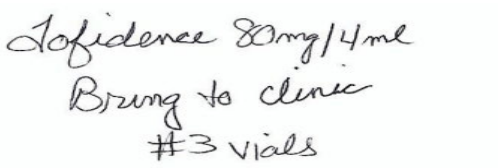
	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)
	• Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* 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?	• 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. Tofidence Study (Conducted on October 14, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Tofidence 200mg/10ml 4mg/kg IV every 2 weeks	Tofidence 80 mg/4 mL Bring to clinic #3 vials
Outpatient Prescription:  Tofidence 80mg/4ml Bring to clinic #3 vials	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Tofidence	

FDA Prescription Simulation Responses (Aggregate Report)

266 People Received Study
94 People Responded

Total	27	27	17	23	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
ALBIDANCE	0	0	1	0	1
DOFIDENCE	0	0	0	2	2
FLODIDENCE	0	0	0	1	1
FOFIDENCE	1	0	0	0	1
HELBIDAS	0	0	1	0	1
JOFIDENCE	0	0	0	1	1
LODFIDNECE	0	0	0	1	1
LOFIDENCE	0	0	0	7	7

TELFIDENCE	0	0	2	0	2
TOFIDANCE	0	0	1	0	1
TOFIDENCE	25	27	5	9	66
TOFIDENCE 80MG/4ML	0	0	0	1	1
TOFIDENEE	0	0	0	1	1
TOFYDANCE	0	0	1	0	1
TOFYDTZ	0	0	1	0	1
TOVIDANCE	0	0	2	0	2
TOVIDENCE	0	0	2	0	2
TOVYDANCE	0	0	1	0	1
TROFIDENCE	1	0	0	0	1

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

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[f]: Dose varies	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.	Tofidence	100	Name subject of review.
2.	Tusscidin PE	74 (phonetic =78)	Name identified in RxNorm database. Product is deactivated per RedBook and no generic equivalents are available.
3.	Tussiden C	74 (phonetic =78)	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.

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.	Prevident	63 (phonetic=70)
2.	Mastic Dent	58

[f] Rheumatoid Arthritis: Recommended Adult Intravenous Dosage: When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Polyarticular Juvenile Idiopathic Arthritis: Recommended Intravenous PJIA Dosage Every 4 Weeks, Patients less than 30 kg weight-10 mg per kg, Patients at or above 30 kg weight-8 mg per kg, Systemic Juvenile Idiopathic Arthritis: Recommended Intravenous SJIA Dosage Every 2 Weeks, Patients less than 30 kg weight-12 mg per kg, Patients at or above 30 kg weight-8 mg per kg

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: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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.	Otocidin	67 (orthographic =71)	This name pair has sufficient orthographic and phonetic differences.
2.	Triesence	66	This name pair has sufficient orthographic and phonetic differences.
3.	Tussiden DM	66 (phonetic=74)	This name pair has sufficient orthographic and phonetic differences.
4.	Besivance	64 (Phonetic=79)	Both names start with different letters (T vs. B). Additionally, the upstroke letters in the third ('f') and fifth position ('d') of Tofidence provide for sufficient orthographic differences between this name pair. Phonetically, the first syllables ("Toe" vs. "Bes") offer some difference in pronunciation. In addition to the orthographic and phonetic differences, the following product characteristics would help to mitigate the error:

[g]Recommended Adult Intravenous Dosage: When used in combination with DMARDs or as monotherapy the recommended starting dose is 4 mg per kg every 4 weeks followed by an increase to 8 mg per kg every 4 weeks based on clinical response. Polyarticular Juvenile Idiopathic Arthritis: Recommended Intravenous PJIA Dosage Every 4 Weeks, Patients less than 30 kg weight-10 mg per kg, Patients at or above 30 kg weight-8 mg per kg, Systemic Juvenile Idiopathic Arthritis: Recommended Intravenous SJIA Dosage Every 2 Weeks, Patients less than 30 kg weight-12 mg per kg, Patients at or above 30 kg weight-8 mg per kg.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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
			• Tofidence is available in multiple strengths [80 mg/4 mL (20 mg/mL), 200 mg/10 mL (20 mg/mL), and 400 mg/20 mL (20 mg/mL)] whereas Besivance is available in a single strength of 6 mg/mL (0.6%). The strengths do not overlap, if included on a prescription/ medication order. • Tofidence is an intravenous infusion prepared and administered by health care providers and dosed based on body weight every 2 or 4 weeks indefinitely; it would be prescribed as infuse X mg once every 2 weeks or every 4 weeks on a patient order. Besivance is an ophthalmic solution dosed three times a day, 4 to 12 hours apart for 7 days; it would be prescribed as instill 1 drop to affected eye three times a day, 4 to 12 hours apart for 7 days. Therefore, there is no overlap in the prescribed dose, frequency of administration, dosage form, or route of administration (if included on a prescription/medication order) between the two products.
5.	Kepivance	64 (phonetic=78)	Orthographically, both names begin with different letters 'T' vs 'K' and Tofidence has an upstroke letter in its fifth position ('d') that is absent in Kepivance providing for some orthographic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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 first syllables ("Toe" vs. Kep") sound different. In addition to the orthographic and phonetic differences, the following product characteristics would help to mitigate the error: • Tofidence has varied doses (4 mg/kg, 8 mg/kg, 10 mg/kg, or 12 mg/kg) depending on the indication whereas Kepivance is dosed at 60 mcg/kg/day. Therefore, there is no overlap in doses between both products. • Frequency of administration of Tofidence is either every 2 weeks or every 4 weeks whereas frequency of Kepivance is once daily for 3 consecutive days before and 3 consecutive days after myelotoxic therapy for a total of 6 doses. The frequency of administration for Tofidence needs to be specified on a prescription/medication order and there is no overlap in frequency of administration between both products.
6.	Body Essence	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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.	Tecfidera	62	This name pair has sufficient orthographic and phonetic differences.
8.	Intelence	62	This name pair has sufficient orthographic and phonetic differences.
9.	Povidex	62 (phonetic=70)	This name pair has sufficient orthographic and phonetic differences.
10.	Tusscidin DM	62 (phonetic=73)	This name pair has sufficient orthographic and phonetic differences.
11.	Neocidin	61	This name pair has sufficient orthographic and phonetic differences.
12.	Ethedent	60	This name pair has sufficient orthographic and phonetic differences.
13.	Ketotifen	60	This name pair has sufficient orthographic and phonetic differences.
14.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
15.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
16.	Otic Edge	60	This name pair has sufficient orthographic and phonetic differences.
17.	Tusscidin	60	This name pair has sufficient orthographic and phonetic differences.
18.	Tussidin DM	60 (phonetic=73)	This name pair has sufficient orthographic and phonetic differences.
19.	Terfinax	59	This name pair has sufficient orthographic and phonetic differences.
20.	Tussionex	59	This name pair has sufficient orthographic and phonetic differences.
21.	Moxidectin	58	This name pair has sufficient orthographic and phonetic differences.
22.	Two-Dyne	58	This name pair has sufficient orthographic and phonetic differences.
23.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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
24.	Articadent	58	This name pair has sufficient orthographic and phonetic differences.
25.	Ruxience	58	This name pair has sufficient orthographic and phonetic differences.
26.	Tirofiban	58	This name pair has sufficient orthographic and phonetic differences.
27.	Benzodent	58	This name pair has sufficient orthographic and phonetic differences.
28.	Tepadina	58	This name pair has sufficient orthographic and phonetic differences.
29.	Lidosense	58	This name pair has sufficient orthographic and phonetic differences.
30.	Cavirinse	58 (phonetic=72)	This name pair has sufficient orthographic and phonetic differences.
31.	Femcon Fe	57	This name pair has sufficient orthographic and phonetic differences.
32.	Dothiepin	57	This name pair has sufficient orthographic and phonetic differences.
33.	Focinvez***	57	This name pair has sufficient orthographic and phonetic differences.
34.	Ivosidenib	57	This name pair has sufficient orthographic and phonetic differences.
35.	Vicodin ES	57	This name pair has sufficient orthographic and phonetic differences.
36.	Tocainide	56	This name pair has sufficient orthographic and phonetic differences.
37.	Toremifene	56 (orthographic =71)	This name pair has sufficient orthographic and phonetic differences.
38.	Cefditoren	56	This name pair has sufficient orthographic and phonetic differences.
39.	Tascenso ODT	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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
40.	Topicaine	56	This name pair has sufficient orthographic and phonetic differences.
41.	Solifenacin	56	This name pair has sufficient orthographic and phonetic differences.
42.	Tofacitinib	56	This name pair has sufficient orthographic and phonetic differences.
43.	Cogentin	56	This name pair has sufficient orthographic and phonetic differences.
44.	Ceftibuten	56	This name pair has sufficient orthographic and phonetic differences.
45.	Doripenem	56	This name pair has sufficient orthographic and phonetic differences.
46.	Timoptic-XE	56	This name pair has sufficient orthographic and phonetic differences.
47.	Codegest	56	This name pair has sufficient orthographic and phonetic differences.
48.	Trokendi	56	This name pair has sufficient orthographic and phonetic differences.
49.	Fertinex	56	This name pair has sufficient orthographic and phonetic differences.
50.	Mentadent	56	This name pair has sufficient orthographic and phonetic differences.
51.	Tepotinib	56	This name pair has sufficient orthographic and phonetic differences.
52.	Cetazone T	56	This name pair has sufficient orthographic and phonetic differences.
53.	Coricidin	56	This name pair has sufficient orthographic and phonetic differences.
54.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
55.	Trisenox	56	This name pair has sufficient orthographic and phonetic differences.
56.	Teveten Hct	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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
57.	Tafamidis	56	This name pair has sufficient orthographic and phonetic differences.
58.	Tribenzor	56	This name pair has sufficient orthographic and phonetic differences.
59.	Tolectin	55	This name pair has sufficient orthographic and phonetic differences.
60.	Tolectin 600	55	This name pair has sufficient orthographic and phonetic differences.
61.	Detectnet	55	This name pair has sufficient orthographic and phonetic differences.
62.	Deconex	55	This name pair has sufficient orthographic and phonetic differences.
63.	Nitrogen, NF	55	This name pair has sufficient orthographic and phonetic differences.
64.	Biofed-PE	55	This name pair has sufficient orthographic and phonetic differences.
65.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
66.	Cefotetan	55	This name pair has sufficient orthographic and phonetic differences.
67.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.
68.	Hycofenix	55	This name pair has sufficient orthographic and phonetic differences.
69.	Polytine D	55	This name pair has sufficient orthographic and phonetic differences.
70.	Ctx3 Rinse	55	This name pair has sufficient orthographic and phonetic differences.
71.	Ctx4 Rinse	55	This name pair has sufficient orthographic and phonetic differences.
72.	Desitin	55	This name pair has sufficient orthographic and phonetic differences.
73.	(b) (4) ***	55	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Tofidence Nonproprietary name: tocilizumab-xxxx Dosage form: injection Strength(s): 80 mg/4 mL (20 mg/mL) 200 mg/10 mL (20 mg/mL) 400 mg/20 mL (20 mg/mL) Usual Dose[g]: Dose varies	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
74.	Tussin CF	55	This name pair has sufficient orthographic and phonetic differences.
75.	Tussin PE	55	This name pair has sufficient orthographic and phonetic differences.
76.	T-Tussin PE	55	This name pair has sufficient orthographic and phonetic differences.
77.	Tobradex	55	This name pair has sufficient orthographic and phonetic differences.
78.	Tascenso	55	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.	Motifene	54
2.	Ticlopidine	54
3.	Tia Doce	54
4.	Iodent	53
5.	Otodine	53
6.	Tri-Dec	53
7.	Cifostodine	52
8.	Codeine	52
9.	Octenidine	52
10.	Tridione	52
11.	Romifidine	52
12.	Tencet	53
13.	Tofranil	51
14.	Ide-Cet	50
15.	Lofexidine	50
16.	Octodrine	50
17.	Triafed & Codeine	50
18.	Triiodide Ion	50

No.	Name	POCA Score (%)
19.	Actified W/Codeine	47
20.	Etidocaine	47
21.	Tolnaftate	46
22.	Actified with Codeine	44
23.	Ectoine	44
24.	Fiorcet w/Codeine	43

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

No.			Failure preventions
1.	(b) (4) ***	66	Proposed proprietary name for BLA 761127 and IND 129198 found unacceptable by DMEPA (OSE#2019-35994384 and 2019-33884038 dated 02/21/2020) due to similarity with marketed and discontinued products. BLA 761127 approved under the proprietary name, Daxxify.
2.	Mycocide NS	65	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
3.	(b) (4) ***	65	Proposed proprietary name for IND 117192 found unacceptable by DMEPA (OSE# 2017-13269234). NDA 210933 approved under the proprietary name, Eysuvis.
4.	Cortidex	62	International product marketed in Mexico, Indonesia, and Brazil.
5.	Pepsodent	62	International product marketed in Canada.
6.	(b) (4) ***	61	Proposed proprietary name withdrawn by the Applicant. NDA 209483 approved under the proprietary name, Impoyz.
7.	(b) (4) ***	61	(b) (4)
8.	Doriden	60	Discontinued per Drugs@FDA. NDA 009519 withdrawn FR effective April 26, 1996.
9.	Trideceth-10	60	Product is not a drug. It is a chemical used in cosmetics.

No.			Failure preventions
10.	Trideceth-12	60	Product is not a drug. It is a chemical used in cosmetics.
11.	Trideceth-3	60	Product is not a drug. It is a chemical used in cosmetics.
12.	Trideceth-5	60	Product is not a drug. It is a chemical used in cosmetics.
13.	Trideceth-6	60	Product is not a drug. It is a chemical used in cosmetics.
14.	Trideceth-8	60	Product is not a drug. It is a chemical used in cosmetics.
15.	Trideceth-9	60	Product is not a drug. It is a chemical used in cosmetics.
16.	Stomodine F	60	Veterinary Drug.
17.	Tricodene	59 (orthographic =78)	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
18.	(b) (4)***	59	Proposed proprietary name for IND 116917 found unacceptable by DMEPA (OSE# 2021-1044724347). A new name, Iyuzeh*** has been found conditionally acceptable (OSE PNR ID# 2022-1044724739 for NDA 216472 on October 31, 2022.
19.	Kenocidin	59	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
20.	Denti-Rinse	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Etofenamate	58	International drug product marketed in many countries throughout Asia, Europe and South America.
22.	Soft Dine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Etofamide	58	International drug product formerly marketed in Brazil, Philippines, and Mexico.
24.	Disofenin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
25.	Defencin CP	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.			Failure preventions
26.	Solfenacin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Toceranib	58	Veterinary drug.
28.	Kepvance	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Clofezone	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	Tricetin	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Tussizone-12 RF	56	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
32.	Dodecene	56	Product is not a drug. It is an alkene belonging to the family of acyclic alkenes, which functions as plasticizers, surfactant, resins, flavor, additive, and lubricant.
33.	Etofylline	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Tiadenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Isodeceth-6	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	Moditen	56	International product marketed in Italy, Venezuela, Hungary, Russia, and Ukraine and formerly marketed in Canada and various European countries.
37.	Nicotinex	56	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
38.	Chenocedon	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Fenipentol	56	International drug product marketed in Italy, Germany, and other countries.

No.			Failure preventions
40.	Isocetane	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Profender	56	Veterinary drug.
42.	Prothiaden	56	International drug product marketed in Australia, India, Malaysia, South Africa, Japan, United Kingdom, Belgium, Denmark, Ireland, France, Netherlands, and Czech Republic; and formerly marketed in several countries including Hong Kong, New Zealand, Philippines, Singapore, Thailand, and Spain.
43.	(b) (4) ***	56	(b) (4)
44.	Tri Vent HC	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Epridient	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
46.	Timentin	56	Brand discontinued with no generic equivalents available. NDA #050590; ANDA #062691 withdrawn FR effective 07/21/2017.
47.	Tormentil	56	Homeopathic agent. Product not identified in commonly used databases.
48.	Tomudex	56	International product marketed in Canada and formerly marketed in Spain, Netherlands, Turkey, Greece, Belgium, Mexico, Italy, Switzerland, Singapore, United Kingdom, France, Hungary, Czech Republic, Australia, Brazil, Austria, Philippines, Finland, Hong Kong, South Africa, Venezuela, and Sweden.
49.	Telavancin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	Surgident	56	International product marketed in Switzerland.

No.			Failure preventions
51.	Kliovance	56	International product marketed in Australia, New Zealand, and the United Kingdom.
52.	Tussiphen DM	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	Superdent	56	International drug marketed in United Kingdom.
54.	Detomidine	55	Veterinary drug.
55.	Tridecane	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	Tilidine	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
57.	Tolfenamic Acid	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
58.	Sulfide Ion	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
59.	Neo-Fradin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	Dofetilde	66
2.	(b) (4) ***	64
3.	Povidone K60	64
4.	Povidone K29-32	64
5.	Povidone K25-28	64
6.	Povidone K25	64
7.	Povidone K17	64
8.	Povidone K15	64

[h]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.	Dostinex	62
10.	Noxivent	62
11.	Cophene No. 2	62
12.	Povidone	61
13.	Povidine	60
14.	Cefonicid	60
15.	(b) (4) ***	60
16.	Diatensec	60
17.	Fucidin	60
18.	Definity	60
19.	Combivent	60
20.	Cophene-X	60
21.	(b) (4) ***	59
22.	Lidosense	58
23.	Oxivent	58
24.	Pyocidin	58
25.	Nafrinse	58
26.	Cefdinir	57
27.	Difenoxin	57
28.	Cefovecin	57
29.	Semilente	57
30.	Desenex	57
31.	Consensi	57
32.	Unitensen	56
33.	Cortenema	56
34.	Folivane-F	56
35.	Isophen-DF	56
36.	Sensodyne	56
37.	Doxidan	56
38.	(b) (4) ***	56
39.	Cophene-X-P	56
40.	Dupixent	56
41.	Docetaxel	56
42.	Cefetamet	56
43.	Macitentan	56
44.	Nasopen PE	56
45.	Copper Edta	56
46.	Dextenza	56
47.	Baciguent	56
48.	Physiotens	56
49.	Cosamin DS	56

No.	Name	POCA Score (%)
50.	Unitensin	56
51.	Diphentann D	55
52.	(b) (4) ***	55

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SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

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:	6/16/2023
Responsible OND Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761354
Product Name and Strength:	Tofidence (tocilizumab-bavi) injection 80 mg/4 mL, 200 mg/10 mL, and 400 mg/20 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Biogen MA Inc. (Biogen)
FDA Received Date:	September 29, 2022
Nexus NPNS ID #:	2022-126
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Acting Director:	Irene Z Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Biogen for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761354.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On September 29, 2022, Biogen submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Biogen also provided their own findings, evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Biogen:

Table 1. Suffixes submitted by Biogen***	
1.	bavi
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for Suffix Review BLA 761354. Cambridge (MA): Biogen MA Inc.; 2022 Sep 29. Available from: \\CDSESUB1\EVSPROD\bla761354\0001\m1\us\118-prop-names\prop-names-suffixreview.pdf

We reviewed Biogen's proposed suffixes in the order of preference listed by Biogen, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 tocilizumab-bavi

Biogen's first proposed suffix, -bavi, is comprised of 4 distinct letters.

We determined that the proposed suffix -bavi, 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 1 ANALYSIS

These findings were shared with OPDP. On June 15, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Rheumatology and Transplant Medicine (DRTM) on June 16, 2023.

4 CONCLUSION

We find Biogen's proposed suffix -bavi acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to tocilizumab-bavi. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Biogen MA Inc.

We find the nonproprietary name, tocilizumab-bavi, conditionally acceptable for your proposed product. Should your 351(k) BLA be approved during this review cycle, tocilizumab-bavi 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.

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

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