CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761342Orig1s000

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:	4/27/2023
Responsible OND Division:	Division of Hematologic Malignancies 2 (DHM 2)
Application Type and Number:	BLA 761342
Product Name and Strength:	Talvey (talquetamab-tgvs) injection 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Janssen Biotech, Inc. (Janssen)
Nexus NPNS ID #:	2022-159
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761342.

1.1 Regulatory History

Janssen was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

talquetamab-tgvs

FDA generated a four-letter suffix, -tgvs. This suffix was evaluated using the principles described in the applicable guidance[b].

We determined that the FDA-generated suffix -tgvs, 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 April 26, 2023, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) on April 27, 2023.

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[a] Harris, D. General Advice Letter for BLA 761342. Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US) 2023 Feb 06.
[b] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

4 CONCLUSION

We find the suffix -tgvs conditionally acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to talquetamab-tgvs. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Janssen Biotech, Inc.

We find the nonproprietary name, talquetamab-tgvs, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, talquetamab-tgvs 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 this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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
04/27/2023 02:38:05 PM

CHI-MING TU
04/27/2023 05:00:08 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)

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

Date of This Review:	February 28, 2023
Application Type and Number:	IND 133811 and BLA 761342
Product Name and Strength:	Talvey (talquetamab-xxxx[a]) Injection, 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Janssen Research & Development, LLC (Janssen)
PNR ID #:	2022-1044724561 and 2022-1044724880
DMEPA 2 Safety Evaluator:	Christina Topper, PharmD, BCPS
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, FISMP, BCPS

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder talquetamab-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received under IND 133811 on April 26, 2022 and under BLA 761342 on December 9, 2022.

- Intended Pronunciation: tal' vay
- Nonproprietary Name: talquetamab-xxxx
- Indication of Use: Treatment of adult patients with relapsed or refractory multiple myeloma (RRMM), who have previously received at least 4 prior therapies, including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 monoclonal antibody.
- Route of Administration: Subcutaneous
- Dosage Form: Injection
- Strength: 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL
- Dose and Frequency: 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks after completion of the step-up dosing schedule
    - Step-up Phase Weekly Dosing Schedule:
        - Day 1: 0.01 mg/kg
        - Day 3: 0.06 mg/kg
        - Day 5: 0.4 mg/kg and then once a week thereafter
    - Step-up Phase Biweekly Dosing Schedule:
        - Day 1: 0.01 mg/kg
        - Day 3: 0.06 mg/kg
        - Day 5: 0.4 mg/kg
        - Day 7: 0.8 mg/kg and then once every 2 weeks thereafter
- How Supplied:
    - One 3 mg/1.5 mL (2 mg/mL) single-dose vial
    - One 40 mg/mL single-dose vial
- Storage: Store refrigerated at 2°C -8°C (36°F to 46°F) prior to use. Store in the original carton to protect from light. Do not freeze the vial.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Talvey would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with OPDP's assessment. The Division of Hematologic Malignancies 2 (DHM 2) did not comment on the findings of OPDP's assessment for Talvey.

2.2 SAFETY ASSESSMENT

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

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

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On January 5, 2023, the Division of Hematologic Malignancies 2 (DHM 2) expressed concerns with the proposed proprietary name of "Talvey" being similar to the proprietary name "Tecvayli" for the recently approved drug teclistamab-cqyv injection.

The two drugs have many similarities, including both are bispecific antibodies, both indicated for treatment of multiple myeloma, and both have similar dosing schedules including step-up dosing and subcutaneous route of administration.

We evaluated this name pair and determined that the risk of confusion will be mitigated because there are sufficient orthographic and phonetic differences.

Orthographically, the names are different lengths (6 letters vs. 8 letters). The ending of the prefix ('Tal' vs. 'Tec') and the infix ('ve' vs. 'vay)'of the name pair has sufficient differences. Further, Talvey ends with a downstroke letter 'y,' while Tecvayli contains an upstroke letter in the suffix 'li' giving the names different shapes when scripted.

Phonetically, the ending sound in the 1st syllables ('al' vs. 'ec') sound different. Talvey is two syllables while Tecvayli has an extra syllable. The last syllable ('vey' vs. 'li') sound different when spoken.

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b USAN stem search conducted on December 12, 2022.

These differences are further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program, which calculates a combined orthographic and phonetic score of 50% suggesting that there is low similarity between these names (see Appendix F).

2.2.4 FDA Name Simulation Studies

Ninety-four (94) practitioners participated in DMEPA's prescription studies for Talvey. 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 80 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 from the Division of Hematologic Malignancies 2 (DHM2). 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%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	71
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 81 names contained in Table 1 determined none of the names will pose a risk for confusion with Talvey as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On February 27, 2023, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

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c POCA search conducted on December 12, 2022 in version 5.1.

3 CONCLUSION

The proposed proprietary name, Talvey, is conditionally acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO JANSSEN RESEARCH & DEVELOPMENT, LLC

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

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

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d National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors Last accessed 10/05/2020.

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

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

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

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

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

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

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

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

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e 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.

   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.

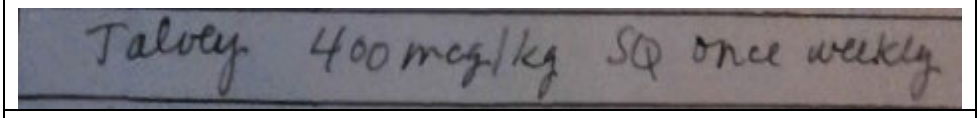
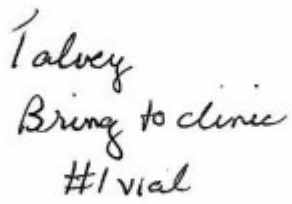
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Talvey Study (Conducted on December 22, 2022)

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

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Talvey

259 People Received Study

94 People Responded

Total	26	26	19	23	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
PALBAE	0	0	1	0	1
PALBAY	0	0	2	0	2
PALVAY	0	0	1	0	1
PALVEY	0	0	1	0	1
TABVEY	0	0	0	1	1
TALBAE	0	0	1	0	1
TALBAY	0	0	1	0	1
TALVA	0	0	1	0	1
TALVAY	0	0	6	0	6
TALVEY	25	26	4	20	75
TALVEY 400 MCG/KG	1	0	0	0	1
TALVEZ	0	0	0	1	1
TALVVEY	0	0	0	1	1
TOLVAY	0	0	1	0	1

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

No.	**Proposed name:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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.	Talvey***	100	Subject of this review.
2.	Bylvay	70	Orthographically, this name pair begins with different letters ('T' vs. 'B'). Bylvay contains the downstroke letter 'y' in the second position which is absent from Talvey providing additional orthographic differences. Phonetically, the first syllables ("Tal" vs. "Byl") sound different. Although the name pair share a numeric similarity in strength (40 mg/mL vs. 400 mcg) both products are available in multiple strengths (3 mg/1.5 mL or 40 mg/mL vs. 200 mcg, 400 mcg, 600 mcg, or 1,200 mcg). Both products are dosed based on weight and thus there may be a potential overlap in dose. However, both products differ in dosage form (injection vs. capsules or pellets), frequency of administration (once weekly or biweekly vs. once daily) and route of administration (subcutaneous vs. oral). Therefore, if included on a prescription/medication order, these differences could provide additional differentiation. Additionally, Talvey is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both pharmacists overlooking the different

No.	**Proposed name:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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.**
			strengths, dosage forms, frequency and routes of administration is minimized.

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.	Aluvea	63
2.	Tyrvaya	60
3.	Aleve-D	58
4.	Talicia	58
5.	E-Solve 2	58
6.	Dalvance	58
7.	Alavert	57
8.	(b) (4) ***	57
9.	C-Solve-2	56
10.	talc	56
11.	Salvax	56
12.	(b) (4) ***	55
13.	(b) (4) ***	58

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:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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.	Talzenna	66	Orthographically, the name pair consist of different number of letters (eight vs. six), and the downstroke letter 'y' in the last position of Talvey which is absent from Talzenna, provides some orthographic differences. Additionally, the suffixes ('-vey' vs. '-na') of this name pair are different. Phonetically, the second syllables ('-vay' vs. '-zen-') of this name pair sound different and Talzenna contains an extra third syllable ('-nah'), which is absent from Talvey. Although both products are oncology agents and may overlap in dose (1 mg), the dose would only overlap for patients with a specific weight of 100 kg receiving the 0.01 mg/kg step-up dose. Additionally, the following differences in product characteristics may help to minimize the risk of errors when indicated on a prescription/medication order: • Talzenna does not overlap with Talvey in strength (0.25 mg or 0.5 mg or 0.75 mg or 1 mg vs. 3 mg/1.5mL (2 mg/mL) or 40 mg/mL) • The products do not overlap in route of administration (oral vs. subcutaneous)

No.	**Proposed name:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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**
			• The products do not overlap in dosage form (capsule vs. Injection) • The products do not overlap in frequency of administration (once daily vs. once weekly or biweekly).
2.	Ztalmy	64	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	62	This name pair has sufficient orthographic and phonetic differences.
4.	Stalevo	62	This name pair has sufficient orthographic and phonetic differences.
5.	Stalevo 100	62	This name pair has sufficient orthographic and phonetic differences.
6.	Stalevo 125	62	This name pair has sufficient orthographic and phonetic differences.
7.	Stalevo 150	62	This name pair has sufficient orthographic and phonetic differences.
8.	Stalevo 200	62	This name pair has sufficient orthographic and phonetic differences.
9.	Stalevo 50	62	This name pair has sufficient orthographic and phonetic differences.
10.	Stalevo 75	62	This name pair has sufficient orthographic and phonetic differences.
11.	Taltz	60	Orthographically, while 1 participant from the outpatient written portion of the FDA Prescription Simulation responded with “Talvez”, the infixes (‘t’ vs. ‘ve’) provide some orthographic differences. Phonetically, the suffixes (‘-tz’ vs. ‘-vay’) sound different.

No.	**Proposed name:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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**
			Although Talvey and Taltz may overlap in dose (20 mg 40 mg and 80 mg), the dose would only overlap in patients with specific weights of 25 kg, 50 kg and 100 kg. However, given the proposed Talvey is for adult patients with relapsed or refractory multiple myeloma, specific weight of 25 kg seems unlikely for adults. Additionally, Talvey and Taltz share the same dosage form (Injection) and route of administration (subcutaneous), however, the following differences in product characteristics may help to minimize the risk of errors when indicated on a prescription/medication order: • Taltz does not overlap with Talvey in strength (80 mg/mL vs. 3 mg/1.5 mL (2 mg/mL) or 40 mg/mL). • Taltz is also supplied in two nonoverlapping presentations (autoinjector and prefilled syringe) where we anticipate the prescriber to indicate on a prescription to assist patients with self-administration. Additionally, Talvey is an injectable oncology drug. Because injectable oncology drugs administered by healthcare professionals typically undergo independent double checks by two pharmacists in the usual clinical setting, the likelihood of both

No.	**Proposed name:** Talvey **Established name:** talquetamab-xxxx **Dosage form:** Injection **Strength(s):** 3 mg/1.5 mL (2 mg/mL) and 40 mg/mL **Usual Dose:** 0.4 mg/kg once weekly or 0.8 mg/kg once every 2 weeks following completion of step-up dosing	**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**
			pharmacists overlooking the different strengths and frequency of administration is minimized. When all the aforementioned mitigations are considered in totality, we find the risk of name confusion is adequately minimized in this case.
12.	Tarpeyo	58	This name pair has sufficient orthographic and phonetic differences.
13.	Silvera	58	This name pair has sufficient orthographic and phonetic differences.
14.	Alvaiz	56	This name pair has sufficient orthographic and phonetic differences.
15.	Balversa	56	This name pair has sufficient orthographic and phonetic differences.
16.	Tarceva	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.	Aleve	54
2.	(b) (4)***	54
3.	Altavera	51
4.	Tecvayli	50
5.	Vital E-500	50
6.	Hyalovet	50
7.	Aventyl	57
8.	Auvelity	46

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.	Del-Vi-A	65	Product discontinued with no generic equivalents available. ANDA 080830 withdrawn FR effective June 22, 1999.
2.	Silver	64	Silver is the name of a natural element. Silver does not exist as a proprietary name on the market.
3.	Talpen	64	International product marketed in the UK.
4.	(b) (4) ***	62	Proposed proprietary name for IND 103031 found unacceptable by DMEPA (OSE # 2020-37029642-1). The product is approved under the proprietary name Tezspire.
5.	(b) (4) ***	62	Proposed (b) (4) found unacceptable on (b) (4) The IND was later withdrawn on (b) (4) No new names have been resubmitted.
6.	Tulaven	61	Veterinary product.
7.	(b) (4) ***	60	Proposed proprietary name withdrawn by the Applicant. NDA 215498 approved under the proprietary name, Bylvay.
8.	Galfer	60	International product marketed in Ireland and the UK.
9.	Tolnate	60	International product marketed in the Philippines.
10.	Telazol	59	Veterinary product.
11.	(b) (4) ***	58	Proposed proprietary name for NDA 211226 found unacceptable by DMEPA (OSE# 2018-23121882). NDA 211226 approved under the proprietary name Khapzory.
12.	(b) (4) ***	58	Proposed proprietary name for IND 135178 found unacceptable by DMEPA (OSE# 2020-41331448). IND 135178 and NDA 215019 approved under the proprietary name Dartisla ODT.
13.	Talacen	58	Name identified by Drugs at FDA and RxNorm databases. However, brand is discontinued with no generic equivalents available. NDA 018458 withdrawn FR effective 08/19/2013.
14.	Tanovea	58	Veterinary product.
15.	Tilade	58	This name was identified by the Drugs at FDA and RxNorm databases. However, the brand is discontinued with no generic equivalent available. NDA 019660 was withdrawn FR effective 07/21/2017 and NDA 020750 was withdrawn FR effective 03/20/2000.

No.	Name	POCA Score (%)	Failure preventions
16.	Travase	57	This name was identified by the Drugs at FDA and RxNorm databases. However, the brand is discontinued with no generic equivalent available. NDA 012828 was withdrawn FR effective 8/19/2013.
17.	Tavegil	56	International product marketed in United Kingdom, Germany, Netherlands, Italy, Denmark, Ireland, and Spain.
18.	Tolazil	56	Veterinary product.
19.	Talwin	55	This name was identified by Drugs at FDA and RxNorm databases. However, brand is discontinued with no generic equivalents available. NDA 016194 withdrawn FR effective 03/04/2022.
20.	Talwin 50	55	This name was identified by Drugs at FDA database. However, brand is discontinued with no generic equivalents available. NDA 016732 withdrawn FR effective 08/19/2013.

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

No.	Name	POCA Score (%)
1.	Atelvia	67
2.	Palmate	61
3.	(b) (4) ***	60
4.	Calcet	60
5.	Dalay	60
6.	Allday	58
7.	Polivy	58
8.	Salzone	58
9.	Valcyte	58
10.	Veltane	58

f 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 (%)
11.	Dalmane	56
12.	Kapvay	56
13.	Nalfed	56
14.	Saljet	56
15.	Sylevia	56
16.	Aclovate	55
17.	Balziva	55
18.	Balziva-21	55
19.	Balziva-28	55
20.	Savella	55
21.	Siltane	55
22.	Wal-Vert	55

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