

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

213586Orig1s000

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:	January 5, 2023
Application Type and Number:	NDA 213586
Product Name and Strengths:	Uzedy (risperidone) extended-release injectable suspension 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Teva Neuroscience (Teva)
PNR ID #:	2022-1044724823
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Uzedy, 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. Teva did not submit an external name study for this proposed proprietary name with this current proprietary name submission. However, Teva previously submitted an external name study, conducted by (b) (4) (b) (4) for the proposed proprietary name, Uzedy, which was reviewed in our initial proprietary name review of Uzedy (see Section 1.1, below).

1.1 REGULATORY HISTORY

Teva initially submitted the proposed proprietary name (b) (4) for review on March 5, 2020 under IND 124384. However, we found the name, (b) (4) ***, unacceptable on April 28, 2020 because of misbranding concerns.^a

Subsequently, Teva resubmitted the name, (b) (4) for reconsideration on June 8, 2020. Upon reconsideration, although we found the name acceptable from a misbranding perspective, our safety review (which was not previously conducted because the name was determined to be misbranded) found the name unacceptable due to orthographic similarities and shared product characteristics with the pending proprietary name, (b) (4) on September 17, 2020.^b

Thereafter, Teva submitted the name, (b) (4) for review on November 19, 2020. However, we found the name, (b) (4) unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) under IND 124384 on May 17, 2021.^c

Thus, Teva submitted the name, (b) (4) for review under NDA 213586 on July 1, 2021. However, we found the name, (b) (4) unacceptable on September 24, 2021 due to orthographic similarities and shared product characteristics with a proposed name that was currently under review.^d

On October 21, 2021, Teva submitted the name, Uzedy, for review. The name was found conditionally acceptable on January 11, 2022.^e However, the Agency issued a Complete Response Letter (CRL) to the NDA on April 15, 2022.

^a Holmes, L. Proprietary Name Review for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Apr 28. Panorama No. 2020-38340112.

^b Holmes, L. Proprietary Name Reconsideration for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Sep 17. Panorama No. 2020-40485490.

^c Holmes, L. Proprietary Name Review for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 May 17. PNR ID No. 2020-1043990615.

^d Holmes, L. Proprietary Name Review for (b) (4) (NDA 213586). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Sep 24. PNR ID No. 2021-1044724048.

^e Howard, C. Proprietary Name Review for Uzedy (NDA 213586). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Jan 11. PNR ID No. 2021-1044724246.

On October 28, 2022, Teva submitted a Class 2 resubmission of the NDA in response to the CRL and concurrently submitted a request for proprietary name review of Uzedy which is the subject of this review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 28, 2022.

- Intended Pronunciation: yoo zeh' dee
- Active Ingredient: risperidone
- Indication of Use: Treatment of schizophrenia
- Route of Administration: subcutaneous
- Dosage Form: extended-release injectable suspension
- Strengths: 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL
- Dose and Frequency:

Prior Therapy	UZEDY Dosage Once Monthly	UZEDY Dosage Once Every Two Months
2 mg of oral risperidone per day	50 mg	100 mg
3 mg of oral risperidone per day	75 mg	150 mg
4 mg of oral risperidone per day	100 mg	200 mg
5 mg of oral risperidone per day	125 mg	250 mg

- How Supplied: Supplied in single-dose kits containing a single-dose prefilled syringe, packaged in a carton with one 21-gauge, 5/8-inch needle
- Storage: Store in refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Uzedy may be stored in unopened original packaging at room temperature, 68°F to 77°F (20°C to 25°C), for up to 90 days. If unopened, Uzedy may be returned to refrigerated storage within 90 days. Once the carton is opened, administer Uzedy or discard.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Uzedy 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 Uzedy. The Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Uzedy.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^f.

2.2.2 *Components of the Proposed Proprietary Name*

Teva indicated in their submission that the proposed proprietary name, Uzedy, “was not derived from any one particular concept.” 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 December 1, 2022, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Uzedy at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

One hundred two (102) practitioners participated in DMEPA’s prescription studies for Uzedy. 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. Nine participants in the verbal portion of the FDA Name Simulation Studies interpreted the last letter of the name as the letter “i”. Appendix B contains the results from the prescription simulation studies.

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search^g identified 10 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated these names in our previous proprietary name review. We note that there is a change in the product strengths such that the volume in mL was expanded from one to two decimal points for most of the product strengths (i.e., 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, and 200 mg/0.56 mL). All other product characteristics remain the same. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We also re-evaluated previously identified names taking into account the change in volume. We agree with the findings from our previous review for the names evaluated previously. Therefore, we did not identify any names not previously analyzed.

^f USAN stem search conducted on December 21, 2022.

^g POCA search conducted on December 21, 2022 in version 5.1.

2.2.6 *Communication of DMEPA's Determination*

On January 5, 2023, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Uzedy, is conditionally acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Safety Regulatory Project Manager, at 240-402-5827.

3.1 COMMENTS TO TEVA NEUROSCIENCE

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

If any of the proposed product characteristics as stated in your submission, received on October 28, 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.

3. **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).

4. **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>).

5. **Division of Medication Errors Prevention and Analysis proprietary name consultation requests**

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.^h

***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)).

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

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 $\geq 70\%$.
- Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
- Low similarity: combined match percentage score $\leq 54\%$.

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 namesⁱ. 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 are often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.
- 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,

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

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 $\geq 70\%$).

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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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	Y/N	Do the syllables have different phonologic processes, such

	upstroke/downstroke letters present in the names?		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 $\geq 55\%$ to $\leq 69\%$).

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.
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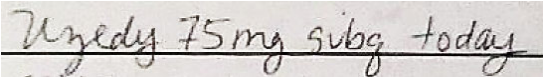
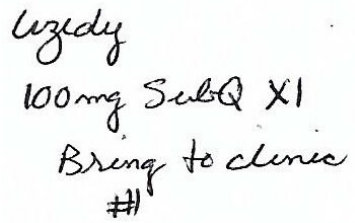
	• Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar 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 $\leq 54\%$).

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. Uzedy Study (Conducted on November 28, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Uzedy 100 mg subcutaneously one time Bring to clinic Dispense one
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Uzedy	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study					
102 People Responded					
Study Name: UZEDY					
Total	26	23	25	28	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
EUZEDI	0	0	1	0	1
IRZIDY	0	0	0	1	1
LEZDY	0	0	0	1	1
LEZEDY	0	0	0	1	1
LIZEDY	0	0	0	2	2
MUSEDY	0	0	1	0	1
MUSIDE	0	0	1	0	1
MUZAYDE	0	0	1	0	1
URZIDY	0	0	0	1	1

USADIE 100 MG SQ ONE TIME	0	0	1	0	1
USAGEI	0	0	1	0	1
USAIDE	0	0	1	0	1
USAIDY	0	0	1	0	1
USEDI	0	0	1	0	1
UZABE	0	0	1	0	1
UZADEE	0	0	1	0	1
UZADY	0	0	3	0	3
UZAYDI	0	0	1	0	1
UZEDEY	0	0	1	0	1
UZEDI	0	0	2	0	2
UZEDY	23	23	0	15	61
UZEGGY	0	0	1	0	1
UZIDY	0	0	0	7	7
UZYDI	0	0	1	0	1
UZYEDY	1	0	0	0	1
VUEZADE	0	0	1	0	1
VYEDY	1	0	0	0	1
VZEDY	1	0	0	0	1
YOUZADE	0	0	1	0	1
YUSIDY	0	0	1	0	1
YUZADI	0	0	1	0	1
YUZEDI	0	0	1	0	1

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/

LORETTA HOLMES
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MADHURI R PATEL
01/05/2023 11:53:24 AM

MISHALE P MISTRY
01/05/2023 12:15:35 PM

Feb 25, 2022

Date of this review is January 11, 2022. The cover page for the review inadvertently had the incorrect date.

PROPRIETARY NAME REVIEW

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Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Teva Neuroscience Inc. (TEVA)
PNR ID #:	2021-1044724246
DMEPA 1 Safety Evaluator:	Corwin D. Howard, Pharm D, RPh
DMEPA 1 Team Leader:	Sevan H. Kolejian, PharmD, MBA, BCPPS
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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Teva then submitted the name, (b) (4) for review on November 19, 2020. However, we found the name, (b) (4) unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) under IND 124384 on May 17, 2021.^c

Thereafter, Teva submitted the name, (b) (4) for review under NDA 213586 on July 1, 2021. However, we found the name, (b) (4) unacceptable due to orthographic similarities and overlapping product characteristics with the pending proprietary name (b) (4) on September 24, 2021.^d

Thus, TEVA submitted the name, Uzedy, for review on October 21, 2021. However, we note that the applicant stated in the proprietary name submission that the previously submitted proposed proprietary name, (b) (4) remains their first choice for the product also stating the previously submitted name, (b) (4) remains their second choice for the product if either names becomes available.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 21, 2021.

- Intended Pronunciation: yoo zeh' dee

^a Holmes, L. Proprietary Name Review for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2020 Apr 28. Panorama No. 2020-38340112.

^b Holmes, L. Proprietary Name Review for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2020 Sep 17. Panorama No. 2020-40485490.

^c Holmes, L. Proprietary Name Review for (b) (4) (IND 124384). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 May 17. PNR ID No. 2021-1043990615.

^d Holmes, L. Proprietary Name Review for (b) (4) (NDA 213586). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 Sep 24. PNR ID No. 2021-1044724048.

- Active Ingredient: risperidone
- Indication of Use: Treatment of schizophrenia
- Route of Administration: Subcutaneous injection
- Dosage Form: extended-release injectable suspension
- Strength: 50 mg/0.1 mL, 75 mg/0.2 mL, 100 mg/0.3 mL, 125 mg/0.4 mL, 150 mg/0.4 mL, 200 mg/0.6 mL, 250 mg/0.7 mL
- Dose and Frequency:
 - Once a month; 50 mg, 75 mg, 100 mg or 125 mg
 - One every 2 months: 100 mg, 150 mg, 200 mg or 250 mg
- How Supplied: Single-use, 1 mL, leur lock, pre-filled syringe, protected from light in an outer carton.
- Storage: Store in refrigerated conditions (2°C to 8°C), protected from light and kept in the outer carton until use. If needed, the product may be stored in unopened original packaging at room temperature (20°C to 25°C) for up to 90 days.
- Reference Listed Drug/Reference Product: Risperdal (risperidone), NDA 020272

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Uzedy would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Uzedy.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

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

2.2.2 *Components of the Proposed Proprietary Name*

TEVA indicated in their submission that the proposed proprietary name, Uzedy, is “not derived from any one particular concept.” This proprietary name is comprised of a single word that does

^e USAN stem search conducted on November 16, 2021.

not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On November 22, 2021, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Uzedy at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-eight (98) practitioners participated in DMEPA's prescription studies for Uzedy. In the voice study, three participants misinterpreted Uzedy for 'Useti', 'Uzeti', and 'Uzety'. Additionally, in the voice study two participants misinterpreted Uzedy for 'Nuzetti', 'Uzedi', and 'Yuzedi'. 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^f identified nine names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the nine names retrieved from our POCA search and three names retrieved from (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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	7
Low similarity name pair: combined match percentage score $\leq 54\%$	4

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

Our analysis of the 12 names contained in Table 1 determined none of the names will pose a risk for confusion with Uzedy as described in Appendices C through H.

^f POCA search conducted on November 16, 2021 in version 4.4.

2.2.8 *Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA 1 communicated our findings to the Division of Psychiatry (DP). At that time, we also requested additional information or concerns that could inform our review. On January 3, 2022 the Division of Psychiatry (DP) stated no additional concerns with the proposed proprietary name, Uzedy.

3 CONCLUSION

The proposed proprietary name, Uzedy, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO TEVA NEUROSCIENCE INC.

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

If any of the proposed product characteristics as stated in your submission, received on October 21, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. USAN Stems (<https://www.ama-assn.org/about/united-states-adopted-names-approved-stems>)

USAN Stems List contains all the recognized USAN stems.

2. *Phonetic and Orthographic Computer Analysis (POCA)*

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm

(<http://www.nlm.nih.gov/research/umls/rxnorm/overview.html>).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁸

⁸ 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 54\%$.

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^h. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

- d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND) and/or Office of Generic Drugs (OGD), ONDQA or OBP for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the safety evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

Additionally, other review disciplines opinions such as ONDQA or OBP may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary reviewer assigned to evaluate the proposed proprietary name is responsible for considering the collective findings and provides an overall risk assessment of the proposed proprietary name.

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

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? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 as 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 $\geq 55\%$ to $\leq 69\%$).

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.

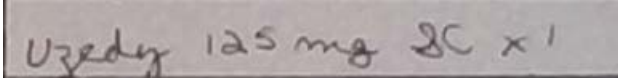
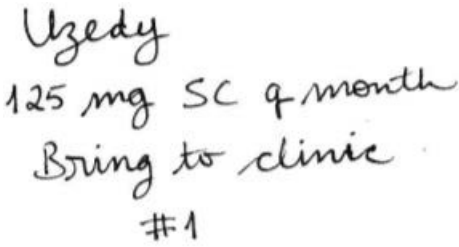
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Uzedy Study (Conducted on November 19, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Uzedy 125 mg Bring to clinic Dispense #1 syringe
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Uzedy	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Uzedy					
As of Date 11/29/2021 263 People Received Study 98 People Responded					
Study Name: Uzedy					
Total	27	19	27	25	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
MUSETTI	0	0	1	0	1
MUZETI	0	0	1	0	1
NEUZETI	0	0	1	0	1
NUZEDY	0	0	1	0	1
NUZETTI	0	0	2	0	2
NUZETTY	0	0	1	0	1
USETI	0	0	3	0	3
USETTI	0	0	1	0	1
USETTY	0	0	1	0	1
USETY	0	0	1	0	1
USEZDY	0	0	0	1	1
UZEDI	0	0	2	0	2

UZEDY	26	19	1	23	69
UZETI	0	0	3	0	3
UZETTI	0	0	1	0	1
UZETY	0	0	3	0	3
UZIDEE	0	0	1	0	1
VZEDY	1	0	0	1	2
YUJEDI	0	0	1	0	1
YUZEDI	0	0	2	0	2

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

No.	Proposed name: Uzedy Established name: risperidone Dosage form: extended-release injectable suspension Strength(s): 50 mg/0.1 mL, 75 mg/0.2 mL, 100 mg/0.3 mL, 125 mg/0.4 mL, 150 mg/0.4 mL, 200 mg/0.6 mL, 250 mg/0.7 mL Usual Dose: 50 mg, 75 mg, 100 mg or 125 mg subcutaneously once monthly or 100 mg, 150 mg, 200 mg, or 250 mg every two months	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.	Uzedy***	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	N/A	

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

No.	Proposed name: Uzedy Established name: risperidone Dosage form: extended-release injectable suspension Strength(s): 50 mg/0.1 mL, 75 mg/0.2 mL, 100 mg/0.3 mL, 125 mg/0.4 mL, 150 mg/0.4 mL, 200 mg/0.6 mL, 250 mg/0.7 mL Usual Dose: 50 mg, 75 mg, 100 mg or 125 mg subcutaneously once monthly or 100 mg, 150 mg, 200 mg, or 250 mg every two months	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
2.	Eze D.S.	66	This name pair has sufficient orthographic and phonetic differences.
3.	Azedra	56	This name pair has sufficient orthographic and phonetic differences.

4.	Oseni	48	This name pair has sufficient orthographic and phonetic differences.
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Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$)

No.	Name	POCA Score (%)
5.	Uceris	39
6.	Upravi	30

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

No.	Name	POCA Score (%)	Failure preventions
8.	(b) (4)	58	Proposed proprietary name withdrawn by the Applicant. Product approved under the proprietary name, Kynmobi.
9.	(b) (4)	56	Proposed proprietary name found unacceptable by DMEPA (OSE# 2016-10538428 dated 03/21/2017) for IND 124098. Subsequently, the proposed proprietary name Idacio*** was found conditionally acceptable for IND 124098.
10.	(b) (4)	48	(b) (4)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusionⁱ.

No.	Name	POCA Score (%)
11.	(b) (4)	60

ⁱ 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 (%)
12.	Ku-Zyme	59
13.	Rusyde	56

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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:	September 24, 2021
Application Type and Number:	NDA 213586
Product Name and Strengths:	(b) (4) (risperidone) extended-release injectable suspension, 50 mg/0.1 mL, 75 mg/0.2 mL, 100 mg/0.3 mL, 125 mg/0.4 mL, 150 mg/0.4 mL, 200 mg/0.6 mL, and 250 mg/0.7 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Teva Neuroscience (Teva)
PNR ID #:	2021-1044724048
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

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MISHALE P MISTRY
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