CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214835Orig1s000

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:	April 14, 2023
Application Type and Number:	NDA 214835
Product Name and Strengths:	Risvan (risperidone) for extended-release injectable suspension, 75 mg and 100 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Laboratorios Farmacéuticos ROVI, S.A. (ROVI)
PNR ID #:	2023-1044724962
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Risvan, 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. ROVI submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 114843 (see Section 1.1 below).

1.1 REGULATORY HISTORY

ROVI initially submitted the proposed proprietary name, (b) (4)***, on July 25, 2018, under IND 114843. However, we found the name, (b) (4)***, unacceptable on January 16, 2019, due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) Subsequently, ROVI submitted the name, (b) (4)***, for review on April 12, 2019. However, we found the name, (b) (4)**, unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4)***, under IND 114843 on October 9, 2019.[b] Thus, ROVI submitted the name, Risvan, for review under IND 114843 on April 27, 2020. The name Risvan was found conditionally acceptable on October 22, 2020.[c]

However, the sponsor withdrew the proposed proprietary name Risvan on March 8, 2021 and the proposed proprietary name, (b) (4)***, was submitted for review on March 12, 2021 under NDA 214835. We found the name, (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) on June 7, 2021.[d] Thus, ROVI resubmitted the name, Risvan, under NDA 214835 for review on June 25, 2021. We found the name conditionally acceptable on August 24, 2021.[e]

On September 24, 2021, a Complete Response Letter (CRL) was issued for NDA 214835. In response to the CRL, ROVI submitted a Class 2 Resubmission of the NDA and concurrently resubmitted the name Risvan for review on January 18, 2022. The name was found conditionally acceptable on April 7, 2022.[f]

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[a] Holmes, L. Proprietary Name Review for (b) (4)(IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jan 16. Panorama No. 2018-24757186.

[b] Holmes, L. Proprietary Name Review for (b) (4)(IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Oct 09. Panorama No. 2019-30776796.

[c] Holmes, L. Proprietary Name Review for Risvan (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 22. Panorama No. 2020-39501394.

[d] Holmes, L. Proprietary Name Review for (b) (4)(NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jun 7. PNR ID No. 2021-1044723871.

[e] Holmes, L. Proprietary Name Review Memorandum for Risvan (NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 24. Panorama No. 2021-1044724040.

[f] Holmes, L. Proprietary Name Review for Risvan (NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Apr 07. Panorama No. 2022-1044724396.

Subsequently, a CRL was issued for NDA 213825 on July 15, 2022. In response to the CRL, ROVI submitted a Class 2 Resubmission of the NDA on January 27, 2023 and submitted a request for proprietary name review of Risvan on January 30, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 30, 2023.

- Intended Pronunciation: RIZ-VAN
- Active Ingredient: risperidone
- Indication of Use: treatment of schizophrenia in adults
- Route of Administration: intramuscular (deltoid or gluteal)
- Dosage Form: for extended-release injectable suspension
- Strength: 75 mg and 100 mg
- Dose and Frequency: See Table 1 on how to switch to Risvan once monthly (75 mg or 100 mg) given via deltoid or gluteal intramuscular injection. Neither a loading dose nor supplemental oral risperidone doses are recommended when switching. For patients who have never taken risperidone, establish tolerability with daily oral risperidone prior to initiating Risvan.

  Do not administer more than one Risvan dose per month. When a dose of Risvan is missed, administer the next Risvan injection as soon as possible.

Table 1. Recommendations for Switching from Daily Oral Risperidone to RISVAN®

Prior Therapy	Initial RISVAN® Dose	Subsequent RISVAN® Doses
3 mg of oral risperidone per day	Start 75 mg the day after discontinuing prior therapy	Once monthly
4 mg of oral risperidone per day	Start 100 mg the day after discontinuing prior therapy	

- How Supplied: Risvan is supplied in a single-dose kit, packaged in a carton containing the following:
  - One pouch with a sterile syringe (labelled ‘R’) prefilled with risperidone powder and poly (lactide-co-glycolide) acid co- polymer powder and desiccant
  - One pouch with a sterile syringe (labelled ‘S’) prefilled with dimethyl sulfoxide solvent and desiccant pack.
  - Two administration needles, one 21G, 1 inch for deltoid and another 20G, 2 inch for gluteal administration.
- Storage: Store at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F) in the unopened original packaging.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

ROVI indicated in their submission that the proposed proprietary name, Risvan, is *composed of two components, the first, "RIS", derived from the first three letters of the established name of the product, "RISPERIDONE", and a fanciful component, "VAN"*. 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 February 23, 2023, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Risvan at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-nine (89) practitioners participated in DMEPA's prescription studies for Risvan. 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. We note that 15 participants in the verbal portion of the FDA Name Simulation Studies interpreted the letter "s" as the letter "z" in the first syllable. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[h] identified 132 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in

[g] USAN stem search conducted on April 4, 2023.

[h] POCA search conducted on April 4, 2023 in version 5.2.

our previous proprietary name review. 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 note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified two names not previously analyzed. 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. 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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
Low similarity name pair: combined match percentage score ≤54%	0

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

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

2.2.8 Communication of DMEPA's Determination

On April 14, 2023, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Risvan, 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 LABORATORIOS FARMACÉUTICOS ROVI, S.A.

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

If any of the proposed product characteristics as stated in your submission, received on January 30, 2023, 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. [i]

***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)).

[i] 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, Cerner RxNorm, 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[j]. 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.

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,

[j] 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 ≥ 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	**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 ≥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

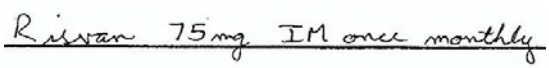
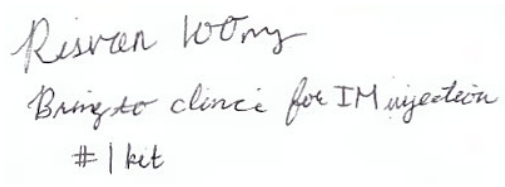
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic 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. Risvan Study (Conducted on March 21, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Risvan 100 mg Bring to clinic for IM injection Dispense 1 kit
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Risvan	

FDA Prescription Simulation Responses (Aggregate Report)

257 People Received Study
89 People Responded

Study Name: Risvan

Total	24	23	22	20	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
RISAVAN	1	0	0	0	1
RISNEAN	0	0	1	0	1
RISVAN	22	23	2	17	64
RISVAN 75MG	1	0	0	0	1
RISVREN	0	0	0	3	3
RIZBAN	0	0	1	0	1
RIZNIA	0	0	1	0	1
RIZNIUM	0	0	1	0	1
RIZVAN	0	0	15	0	15
RYZVAN	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%) – **N/A**

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.	Vutrisiran	56

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

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%) – **N/A**

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.	Arovyn	56	Veterinary product.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[k]. – **N/A**

[k] 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

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/s/

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PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	December 12, 2023
Application Type and Number:	NDA 214835
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Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Laboratorios Farmacéuticos ROVI, S.A. (ROVI)
PNR ID #:	2023-1044725380
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Acting Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Risvan, which was found conditionally acceptable under NDA 214835 on April 14, 2023.[a] On July 27, 2023, a Complete Response Letter (CRL) was issued for NDA 214835. In response to the CRL, ROVI submitted a Class 2 Resubmission of the NDA on September 29, 2023, and concurrently resubmitted the name Risvan for review. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Risvan 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 Risvan. The Division of Psychiatry (DP) did not comment on the findings of OPDP's assessment for Risvan.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The November 16, 2023 search of USAN stems did not find any USAN stems in the proposed proprietary name, Risvan.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On December 12, 2023, we communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Risvan, 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 LABORATORIOS FARMACÉUTICOS ROVI, S.A.

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

---

[a] Holmes, L. Proprietary Name Review for Risvan (NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 APR 14. PNR ID No. 2023-1044724962.

If any of the proposed product characteristics as stated in your submission, received on September 29, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

LORETTA HOLMES
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MISHALE P MISTRY
12/12/2023 02:13:26 PM

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:	April 7, 2022
Application Type and Number:	NDA 214835
Product Name and Strength:	Risvan (risperidone) for extended-release injectable suspension, 75 mg and 100 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Laboratorios Farmacéuticos ROVI, S.A. (ROVI)
PNR ID #:	2022-1044724396
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

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Risvan, 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. ROVI submitted an external name study, conducted by (b) (4) for this proposed proprietary name. The submitted external name study was previously reviewed under IND 114843 (see Section 1.1 below).

1.1 REGULATORY HISTORY

ROVI initially submitted the proposed proprietary name, (b) (4)***, on July 25, 2018, under IND 114843. However, we found the name, (b) (4)***, unacceptable on January 16, 2019, due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) Subsequently, ROVI submitted the name, (b) (4)***, for review on April 12, 2019. However, we found the name, (b) (4) *, unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4)***, under IND 114843 on October 9, 2019.[b] Thus, ROVI submitted the name, Risvan, for review under IND 114843 on April 27, 2020. The name Risvan was found conditionally acceptable on October 22, 2020.[c]

However, the sponsor withdrew the proposed proprietary name Risvan on March 8, 2021 and the proposed proprietary name, (b) (4)***, was submitted for review on March 12, 2021 under NDA 214835. We found the name, (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) on June 7, 2021.[d] Thus, ROVI resubmitted the name, Risvan, under NDA 214835 for review on June 25, 2021. We found the name conditionally acceptable on August 24, 2021.[e]

On September 24, 2021, a Complete Response Letter (CRL) was issued for NDA 214835. In response to the CRL, ROVI submitted a Class 2 Resubmission of the NDA and resubmitted the name Risvan for review. Both were received on January 18, 2022.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 18, 2022.

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[a] Holmes, L. Proprietary Name Review for (b) (4) (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Jan 16. Panorama No. 2018-24757186.

[b] Holmes, L. Proprietary Name Review for (b) (4) (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Oct 09. Panorama No. 2019-30776796.

[c] Holmes, L. Proprietary Name Review for Risvan (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 22. Panorama No. 2020-39501394.

[d] Holmes, L. Proprietary Name Review for (b) (4) (NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jun 7. PNR ID No. 202 4723871.

[e] Holmes, L. Proprietary Name Review Memorandum for Risvan (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 24. Panorama No. 2021-1044724040.

- Intended Pronunciation: RIZ-VAN
- Active Ingredient: risperidone
- Indication of Use: Treatment of schizophrenia in adults
- Route of Administration: Intramuscular (gluteal or deltoid, without distinction)
- Dosage Form: for extended-release injectable suspension
- Strengths: 75 mg and 100 mg
- Dose and Frequency: 75 mg or 100 mg intramuscular (IM) every 4 weeks
- How Supplied: Supplied in a single-dose kit, packaged in a carton containing the following:
    - One pouch with a sterile syringe (labelled 'R') prefilled with risperidone powder and poly (lactide-co-glycolide) acid co- polymer powder
    - One pouch with a sterile syringe (labelled 'S') prefilled with dimethyl sulfoxide solvent
    - Two administration needles, one 21G, 1 inch for deltoid and another 20G, 2-inch for gluteus
- Storage: Store in its unopened original package at room temperature 20°C to 25°C (68°F to 77°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Risvan 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 Risvan.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[f] USAN stem search conducted on March 7, 2022.

2.2.2 Components of the Proposed Proprietary Name

ROVI indicated in their submission that the proposed proprietary name, Risvan, *is composed of two components, the first, "RIS", derived from the first three letters of the established name of the product, "RISPERIDONE", and a fanciful component, "VAN"*. 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 February 2, 2022, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Risvan at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred eight (108) practitioners participated in DMEPA's prescription studies for Risvan. 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. Twelve participants in the verbal portion of the study and one participant in the inpatient portion of the study interpreted the third position letter "s" as the letter "z". 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 131 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. 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 note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified one name not previously analyzed. This name is included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the new name retrieved from our current POCA search. This new name pair is 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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	1

[g] POCA search conducted on March 7, 2022 in version 4.4.

Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the name contained in Table 1 determined the name will not pose a risk for confusion with Risvan as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On April 7, 2022, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Risvan, is 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 LABORATORIOS FARMACÉUTICOS ROVI, S.A.

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

If any of the proposed product characteristics as stated in your submission, received on January 18, 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 ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.

- Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[i]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign 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 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 ≥ 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	**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 ≥55% to ≤69%).

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

Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **<u>with</u>** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • 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. Risvan Study (Conducted on March 11, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Risvan 75 mg IM every 4 weeks	Risvan 100 mg Bring to clinic for IM injection Dispense one kit
Outpatient Prescription: Risvan 100mg Bring to clinic for IM injection #1 kit	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Risvan	

FDA Prescription Simulation Responses (Aggregate Report)

	262 People Received Study
	108 People Responded

Study Name: Risvan

Total	32	26	21	29	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
RESVAN	0	0	1	0	1
REZVAN	0	0	1	0	1
REZVIA	0	0	1	0	1
REZVIAN	0	0	1	0	1
RISBAN	0	0	1	0	1

RISVAN	29	26	3	27	85
RISVAN 100 MG	1	0	0	0	1
RISVARI	1	0	0	0	1
RISVIAN	0	0	1	0	1
RISVIEN	0	0	1	0	1
RIXVAN	1	0	0	1	2
RIZSVANC	0	0	1	0	1
RIZVAN	0	0	6	1	7
RYSVAN	0	0	2	0	2
RYZVAN	0	0	1	0	1
RYZVIAN	0	0	1	0	1

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

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.	(b) (4) ***	56

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

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

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

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[j]. **(N/A)**

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

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/s/

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PROPRIETARY NAME MEMORANDUM

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:	August 24, 2021
Application Type and Number:	NDA 214835
Product Name and Strength:	Risvan (risperidone) for extended-release injectable suspension, 75 mg and 100 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Laboratories Farmaceuticos ROVI, S.A . (ROVI)
PNR ID #:	2021-1044724040
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Risvan, which was found conditionally acceptable under IND 114843 on October 22, 2020.[a] After our initial review, the name Risvan was withdrawn on March 8, 2021 and the proposed proprietary name, (b) (4)***, was submitted for review on March 12, 2021 under NDA 214835. However, we found the name, (b) (4)*** unacceptable due to orthographic similarities and shared product characteristics with the proprietary name, (b) (4) on June 7, 2021.[b] Thus, ROVI resubmitted the name, Risvan, under NDA 214835 for review on June 25, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Risvan 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 Risvan.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The August 13, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Risvan.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We 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 August 20, 2021, the Division of Psychiatry (DP) stated no additional concerns with the proposed proprietary name, Risvan.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Risvan, is acceptable.

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

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[a] Holmes, L. Proprietary Name Review for Risvan (IND 114843). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 22. PNR ID No. 2020-39501394.

[b] Holmes, L. Proprietary Name Review for (b) (4) (NDA 214835). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jun 7. PNR ID No. 2021-1044723871.

3.1 COMMENTS TO LABORATORIES FARMACEUTICOS ROVI, S.A .

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

If any of the proposed product characteristics as stated in your submission, received on June 25, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)
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:	June 7, 2021
Application Type and Number:	NDA 214835
Product Name and Strength:	(b) (4) (risperidone)) for extended-release injectable suspension, 75 mg and 100 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Laboratorios Farmacéuticos ROVI, S.A. (ROVI)
PNR ID #:	2021-1044723871
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA Director:	Lubna Merchant, MS, PharmD

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