CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215487Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 8, 2023
Application Type and Number:	NDA 215487
Product Name and Strength:	Rezenopy (naloxone hydrochloride) nasal spray, 10 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Summit Biosciences Inc. (Summit)
PNR ID #:	2023-1044725451
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Director	Mishale Mistry, PharmD, MPH

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Rezenopy, 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. Summit submitted an external name study, conducted by (b) (4), for this proposed proprietary name.

1.1 REGULATORY HISTORY

Summit previously submitted the proposed proprietary name, (b) (4) ***, under NDA 215487 on July 14, 2023. However, on October 12, 2023, we found the name (b) (4) *** unacceptable due to (b) (4) [a]

Thus, Summit submitted the name, Rezenopy, for review on November 3, 2023 under NDA 215487.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 3, 2023.

- Intended Pronunciation: reh zeh' noe pee
- Active Ingredient: naloxone hydrochloride
- Indication of Use: emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression
- Route of Administration: intranasal
- Dosage Form: nasal spray
- Strength: 10 mg
- Dose and Frequency: one 10 mg (b) (4) mL) spray delivered by intranasal administration into one nostril; requirements for repeat doses depends on amount, type, and route of administration of the opioid being antagonized. Readminister naloxone hydrochloride nasal spray, using a new nasal spray, after 2 minutes (in opposite nostril) if the patient does not respond or responds and then relapses into respiratory depression
- How Supplied: each carton of naloxone hydrochloride nasal spray contains two blister packs; each blister pack contains one device
- Storage: store below 77° F (25°C). Excursions permitted up to 104°F (40°C). Do not freeze or expose to excessive heat above 104°F (40°C). Protect from light
- Reference Listed Drug: Narcan (naloxone hydrochloride injection) NDA 016636

[a] Birkemeier D. Proprietary Name Review for (b) (4) NDA 215487). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 OCT 12. PNR ID No. 2023-1044725241.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Rezenopy 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 Rezenopy. The Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not comment on the findings of OPDP's assessment for Rezenopy.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On December 6, 2023, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Rezenopy at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Sixty-seven practitioners participated in DMEPA's prescription studies for Rezenopy. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 65 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

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[b] USAN stem search conducted on November 7, 2023.

[c] POCA search conducted on November 7, 2023 in version 5.2.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	59
Low similarity name pair: combined match percentage score ≤54%	8

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

Our analysis of the 68 names contained in Table 1 determined none of the names will pose a risk for confusion with Rezenopy as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On December 8, 2023, DMEPA 1 communicated our determination to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP).

3 CONCLUSION

The proposed proprietary name, Rezenopy, is conditionally acceptable.

If you have any questions or need clarifications, please contact Carol Corbie, OSE project manager, at 240-402-1124.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[d]

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

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

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

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

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.	
Orthographic Checklist	Phonetic Checklist

Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

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

	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Rezenopy Study (Conducted on November 13, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription

Medication Order: Rezenopy Instill 1 spray intranasally as needed for suspected opiod overdose Outpatient Prescription: Patient _____ Date 11/13/23 Address _____ ℞ Rezenopy Instill 1 spray (10mg) into one nostril. Repeat dose with a new device after 2 minutes if needed for suspected opioid overdose. #1carton MEDWATCH 1-800-FDA-1088 Refill(s):_____ Dr. _____ DEA No._____ Address _____ Telephone _____ **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** **Rezenopy**	Rezenopy Instill 1 spray (10 mg) into one nostril. Repeat dose with a new device after 2 minutes if needed for suspected opioid overdose. Dispense #1 carton

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Rezenopy
Study Date: November 13, 2023
People Received Study: 229
People Responded: 67

Total	16	20	12	19	67
INTERPRETATION	**INPATIENT**	**OUTPATIENT**	**VOICE**	**CPOE**	**TOTAL**
RESANOBI	0	0	2	0	2
RESENOPI	0	0	1	0	1
RESINOPI	0	0	1	0	1
RESINOPY	0	0	1	0	1
RESONOBI	0	0	1	0	1

REZANOBI	0	0	1	0	1
REZANOPI	0	0	3	0	3
REZANOPY	0	0	1	0	1
REZEMNOPI	0	0	1	0	1
REZENOPY	16	20	0	19	55

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

No.	**Proposed name:** Rezenopy **Established name:** naloxone hydrochloride **Dosage form:** nasal spray **Strength(s):** 10 mg **Usual Dose:** One spray (10 mg) intranasally	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.	Rezenopy	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Refenesen	60
2.	Razadyne	58
3.	Rebinyn	58
4.	Selzentry	58
5.	Rezipres	57
6.	Verzenio	56
7.	Zenpep	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

No.	**Proposed name:** Rezenopy **Established name:** naloxone hydrochloride **Dosage form:** nasal spray **Strength(s):** 10 mg **Usual Dose:** One spray (10 mg) intranasally	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	Reno-Dip	66	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4) ***	65	This name pair has sufficient orthographic and phonetic differences.
3.	Revonto	64	This name pair has sufficient orthographic and phonetic differences.
4.	Ryzneuta	63	This name pair has sufficient orthographic and phonetic differences.
5.	Rezamid	62	This name pair has sufficient orthographic and phonetic differences.
6.	Regen-Cov	61	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Rezenopy **Established name:** naloxone hydrochloride **Dosage form:** nasal spray **Strength(s):** 10 mg **Usual Dose:** One spray (10 mg) intranasally	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
7.	Resinol	60	This name pair has sufficient orthographic differences. Phonetically, Rezenopy has an additional syllable (4 *versus* 3). The endings of the names (noe pee *versus* nol) sound different and offer additional phonetic differences. In addition to the orthographic and phonetic differences, the following product characteristics may help to mitigate the risk of confusion if included on a prescription: • There is no overlap in route of administration (intranasal vs. topical) or dosage form (nasal spray vs. ointment). • In instances where the dose is specified, there is no overlap in dose (one spray or 10 mg once *versus* apply to affected area not more than 3 to 4 times daily) When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
8.	Ryvent	60	This name pair has sufficient orthographic and phonetic differences.
9.	Relenza	59	This name pair has sufficient orthographic and phonetic differences.
10.	Pizensy	58	This name pair has sufficient orthographic and phonetic differences.
11.	Profeno	58	This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4)***	58	This name pair has sufficient orthographic and phonetic differences.
13.	Rezine	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Rezenopy **Established name:** naloxone hydrochloride **Dosage form:** nasal spray **Strength(s):** 10 mg **Usual Dose:** One spray (10 mg) intranasally	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**
14.	Robafen Pe	58	This name pair has sufficient orthographic and phonetic differences.
15.	Levodopa	57	This name pair has sufficient orthographic and phonetic differences.
16.	Regonol	57	This name pair has sufficient orthographic and phonetic differences.
17.	Refenesen Pe	56	This name pair has sufficient orthographic and phonetic differences.
18.	Rextovy	56	This name pair has sufficient orthographic and phonetic differences.
19.	Rezurock	56	This name pair has sufficient orthographic and phonetic differences.
20.	(b) (4)***	55	This name pair has sufficient orthographic and phonetic differences.
21.	Trisenox	56	This name pair has sufficient orthographic and phonetic differences.
22.	(b) (4)***	55	(b) (4)***" is the root name for (b) (4). This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Reno-30	50
2.	Reno-60	50
3.	Ryneze	50
4.	Rexulti	40
5.	Wegovy	36
6.	Rilpivirine	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
1.	(b) (4) ***	64	Previously proposed proprietary name for this NDA (NDA 215487) found unacceptable by DMEPA due to a conflict with a marketed product (OSE# 2023-1044725241 dated October 12, 2023).
2.	Reno M-Dip	62	International product marketed in Canada.
3.	(b) (4) ***	61	Proposed proprietary name for (b) (4)
4.	Ridenol	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Zofenopril	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	(b) (4) ***	59	Proposed proprietary name for BLA 125611 found unacceptable on July 18, 2016. Subsequently, BLA 125611 was approved under the proprietary name Rebinyn.
7.	(b) (4) ***	59	Proposed proprietary name found unacceptable by DMEPA (OSE 2019-34589634). Product approved under proprietary name Seglentis (NDA 213426).
8.	(b) (4) ***	58	(b) (4)
9.	Remnos	58	International product marketed in the United Kingdom.
10.	(b) (4) ***	58	(b) (4)
11.	(b) (4) ***	58	Proposed proprietary name (b) (4) .
12.	Rezipas	58	Brand discontinued with no generic equivalents available. NDA 009052 withdrawn FR effective 09/13/2000.

No.	Name	POCA Score (%)	Failure preventions
13.	(b) (4) ***	58	(b) (4)
14.	(b) (4) ***	57	(b) (4)
15.	(b) (4) ***	57	Proposed proprietary name for BLA 125590 found unacceptable on September 16, 2015. Subsequently, BLA 125590 was approved under the proprietary name Asceniv.
16.	Rotenone	57	Product is not a drug. It is used as an ingredient in insecticides or pesticides.
17.	Renotec	56	Brand discontinued with no generic equivalents available. NDA 017045 withdrawn FR effective 03/13/2009.
18.	Ryzodeg	56	Root name of Ryzodeg 70/30; Ryzodeg 70/30 is discontinued with no generic equivalents available. Additionally, Ryzodeg, is an international product marketed in Australia, Austria, China, Czech Republic, Denmark, Hong Kong, Israel, Japan, Malaysia, Netherlands, Philippines, Poland, Switzerland, Thailand, Turkey, and Ukraine, as well as an international product formerly marketed in Finland and Portugal.
19.	Ryzodeg 70/30	56	Brand discontinued with no generic equivalents available.
20.	Travenol	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Radent	55	International product marketed in New Zealand.
22.	Rederox	55	Veterinary Product.
23.	(b) (4) ***	55	(b) (4)
24.	(b) (4) ***	54	Proposed proprietary name for IND 101399 found unacceptable by DMEPA (OSE# 2014-26293 dated February 25, 2015). BLA 761033 approved under the proprietary name Cinqair.

No.	Name	POCA Score (%)	Failure preventions
25.	Benzopyrene	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	58
2.	Eprozinol	56
3.	Evenity	60
4.	(b) (4) ***	56
5.	Miraphen Pe	55
6.	Oradent	55
7.	Predenema	58
8.	Preven Ec	64
9.	Pro-Vent	58
10.	Serevent	56

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

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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:	October 12, 2023
Application Type and Number:	NDA 215487
Product Name and Strength:	(b) (4) (naloxone hydrochloride) nasal spray, 10 mg
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Summit Biosciences Inc. (Summit)
PNR ID #:	2023-1044725241
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD, FISMP, NREMT
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

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