CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216903Orig1s000

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:	November 8, 2022
Application Type and Number:	NDA 216903
Product Name and Strength:	Prevduo (neostigmine methylsulfate and glycopyrrolate) injection, 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL)
Product Type:	Multiple Ingredient Combination Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Slayback Pharma LLC (Slayback)
PNR ID #:	2022-1044724712
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Prevduo, 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. Slayback submitted an external name study, conducted by [redacted] (b) (4)., for this proposed proprietary name.

1.1 PRODUCT INFORMATION

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

- Intended Pronunciation: Prev-DU-OH
- Active Ingredient: neostigmine methylsulfate and glycopyrrolate
- Indication of Use: Reversal of the effects of non-depolarizing neuromuscular blocking agents (NMBAs) after surgery, [redacted] (b) (4)
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL)
- Dose and Frequency: A dose of 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg of neostigmine (0.014 mg/kg glycopyrrolate) will generally achieve a Train of Four twitch ratio of 90% within 10 to 20 minutes of administration. Dose should be based on the extent of spontaneous recovery that has occurred at the time of administration, the half-life of the NMBA being reversed, and whether there is a need to rapidly reverse the NMBA.
    - The 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) dose is recommended for:
        - Reversal of NMBAs with shorter half-lives, e.g., rocuronium
        - When the first twitch response to the Train of Four stimulus is substantially greater than 10% of baseline when a second twitch is present
    - The 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate) dose is recommended for:
        - Reversal of NMBAs with longer half-lives, e.g., vecuronium or pancuronium
        - When the first twitch response is relatively weak, i.e., not substantially greater than 10% of baseline
        - There is need for more rapid recovery

  Recommended maximum total dose is 0.07 mg/kg neostigmine (equivalent to 0.014 mg/kg glycopyrrolate) or up to 5 mg neostigmine (equivalent to 1 mg glycopyrrolate), whichever is less

- How Supplied: 3 mL single-dose syringe packaged as a pack of 5 syringes
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [See USP Controlled Room Temperature]. Protect from light.
- Reference Listed Drug:
    - NDA 204078 – Bloxiverz (neostigmine methylsulfate)
    - NDA 017558 – Robinul (glycopyrrolate)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Prevduo 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 Prevduo. The Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Prevduo.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Slayback indicated in their submission that the proposed proprietary name, Prevduo, implies a combination product to reverse neuromuscular blockade. This proprietary name is comprised of a single word. We note the proposed proprietary name contains the letter string "pr" which is a commonly used medical abbreviation meaning "per rectum" that may be used on a prescription order. We typically discourage the inclusion of medical abbreviations within proprietary names; however, we evaluated the potential risk of misinterpreting the proposed proprietary name as "Pr [drug name similar to Evduo]" and did not identify any concerns. Thus, we do not object to the inclusion of the letters "Pr" in this case. Other than the abbreviation "pr", the proposed name, Prevduo, does not contain any additional components (i.e., a modifier, dosage form, etc.) that are misleading or can contribute to medication errors.

[a] USAN stem search conducted on August 18, 2022.

2.2.3 Comments from Other Review Disciplines at Initial Review

On September 16, 2022, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Prevduo at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One-hundred and one practitioners participated in DMEPA's prescription studies for Prevduo. 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[b] identified 87 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and (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%	88
Low similarity name pair: combined match percentage score ≤54%	5

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

Our analysis of the 94 names contained in Table 1 determined none of the names will pose a risk for confusion with Prevduo as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On November 8, 2022, DMEPA 1 communicated our determination to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP).

[b] POCA search conducted on August 18, 2022, in version 4.4.

3 CONCLUSION

The proposed proprietary name, Prevduo, is acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO SLAYBACK PHARMA LLC

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

If any of the proposed product characteristics as stated in your submission, received on August 18, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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. [c]

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

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. 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.

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

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

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

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

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

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

   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.

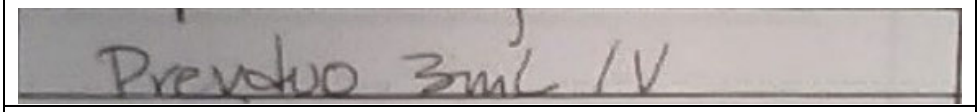
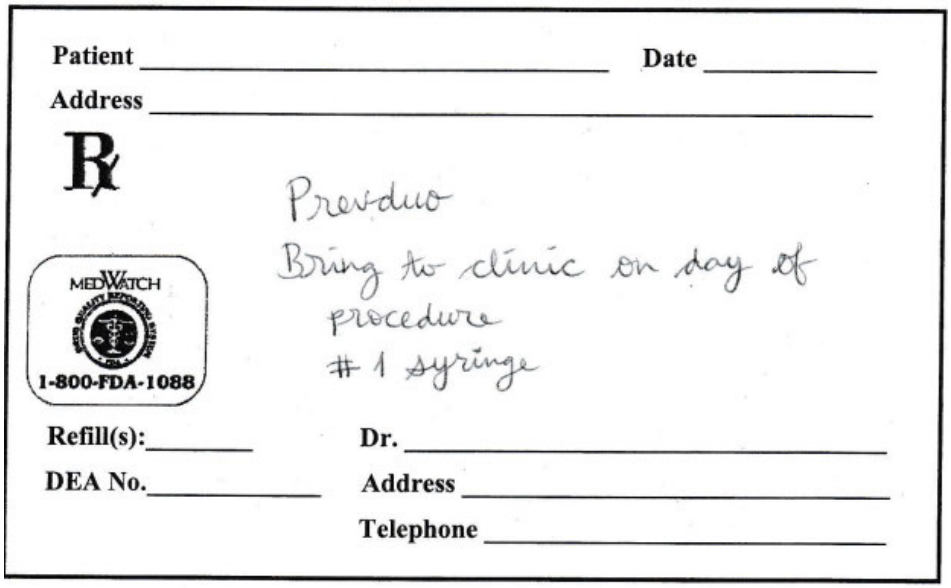
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Prevduo Study (Conducted on August 29, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  	Prevduo Bring to clinic on day of procedure. Dispense one syringe.
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Prevduo	

FDA Prescription Simulation Responses (Aggregate Report)

265 People Received Study
101 People Responded

Study Name: Prevduo

Total	21	28	26	26	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
CREVDUO	0	0	2	0	2
KREM DUO	0	0	1	0	1
PREMDUO	0	0	1	0	1
PREVDILO	0	0	1	0	1
PREVDUO	23	28	19	21	91
PREVDUO 3ML	1	0	0	0	1
PREVDUWO	0	0	1	0	1
PREVTOO	1	0	0	0	1
PREVTUO	1	0	0	0	1
TRANSDO	0	0	1	0	1

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

No.	**Proposed name:** Prevduo **Established name:** neostigmine methylsulfate and glycopyrrolate **Dosage form:** injection **Strength(s):** 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL) **Usual Dose:** 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate)	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.	Prevduo	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.	Pretz-D	64
2.	Prevpac	64
3.	(b) (4) ***	61
4.	Prodium	61
5.	Prevacid	60
6.	M-Predrol	58
7.	Pirnuo	58
8.	Plenvu	58
9.	Prednisol	58
10.	Prelu-2	58
11.	Prevident	58
12.	Revatio	58
13.	Apretude	56
14.	Epiduo	56
15.	Pre-Pen	56
16.	Pretz	56
17.	Prevymis	56
18.	Pre-Op Ii	55

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:** Prevduo **Established name:** neostigmine methylsulfate and glycopyrrolate **Dosage form:** injection **Strength(s):** 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL) **Usual Dose:** 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate)	**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.	Prevnar	69	Orthographically, Prevduo has an upstroke letter 'd' in the fifth position which provides some difference. Phonetically, this name pair has a differing number of syllables (3 *versus* 2) and the infix/suffix of Prevduo (-du-o) sounds different than the suffix of Prevnar (-nar). While both products would be supplied as a prefilled syringe, Prevduo is administered intravenously to reverse neuromuscular blocking agents in a surgical operating room setting typically under direction of an anesthesiologist or a certified registered nurse anesthetist with monitoring to evaluate patient response. Prevnar is a pneumococcal vaccine administered intramuscularly and is typically not stored/administered in the surgical setting. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
2.	Prevnar 13	69	Orthographically, Prevduo has an upstroke letter 'd' in the fifth position which provides some difference.

No.	**Proposed name:** Prevduo **Established name:** neostigmine methylsulfate and glycopyrrolate **Dosage form:** injection **Strength(s):** 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL) **Usual Dose:** 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate)	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
			Phonetically, this name pair has a differing number of syllables (3 *versus* 2) and the infix/suffix of Prevduo (-du-o) sounds different than the suffix of Prevnar (-nar). While both products would be supplied as a prefilled syringe, Prevduo is administered intravenously to reverse neuromuscular blocking agents in a surgical operating room setting typically under direction of an anesthesiologist or a certified registered nurse anesthetist with monitoring to evaluate patient response. Prevnar is a pneumococcal vaccine administered intramuscularly and is typically not stored/administered in the surgical setting. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
3.	Prevnar 20	69	Orthographically, Prevduo has an upstroke letter ‘d’ in the fifth position which provides some difference. Phonetically, this name pair has a differing number of syllables (3 *versus* 2) and the infix/suffix of Prevduo (-du-o) sounds different than the suffix of Prevnar (-nar).

No.	**Proposed name:** Prevduo **Established name:** neostigmine methylsulfate and glycopyrrolate **Dosage form:** injection **Strength(s):** 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL) **Usual Dose:** 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate)	**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**
			While both products would be supplied as a prefilled syringe, Prevduo is administered intravenously to reverse neuromuscular blocking agents in a surgical operating room setting typically under direction of an anesthesiologist or a certified registered nurse anesthetist with monitoring to evaluate patient response. Prevnar is a pneumococcal vaccine administered intramuscularly and is typically not stored/administered in the surgical setting. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
4.	Prempro	66	This name pair has sufficient orthographic and phonetic differences.
5.	Predone	64	This name pair has sufficient orthographic and phonetic differences.
6.	Pred-G	64	This name pair has sufficient orthographic and phonetic differences.
7.	Pred-G S.O.P.	62	This name pair has sufficient orthographic and phonetic differences.
8.	Prosed	62	This name is the root name for "Prosed EC" and "Prosed DS". While it appears that Prosed EC has been discontinued, generic equivalents for Prosed DS are available. This name pair has sufficient orthographic and phonetic differences.
9.	Prehevbrio	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Prevduo **Established name:** neostigmine methylsulfate and glycopyrrolate **Dosage form:** injection **Strength(s):** 3 mg/0.6 mg/3 mL (1 mg/0.2 mg/mL) **Usual Dose:** 0.03 mg/kg neostigmine (0.006 mg/kg glycopyrrolate) to 0.07 mg/kg neostigmine (0.014 mg/kg glycopyrrolate)	**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**
10.	Pred Forte	58	This name pair has sufficient orthographic and phonetic differences.
11.	Prednicot	58	This name pair has sufficient orthographic and phonetic differences.
12.	Provera	57	This name pair has sufficient orthographic and phonetic differences.
13.	Prosed Ds	56	This name pair has sufficient orthographic and phonetic differences.
14.	Revcovi	56	This name pair has sufficient orthographic and phonetic differences.
15.	Pedi-Pro	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Preop	53
2.	Pre-Op	53
3.	Depopred	47

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.	Predcor	69	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
2.	Predsol	67	International product marketed in Australia, Hong Kong, Chile, and Australia and formerly marketed in South Africa, New Zealand, Ireland, and the United Kingdom.
3.	Zuprevo	65	Veterinary product.

No.	Name	POCA Score (%)	Failure preventions
4.	Predfoam	63	International product marketed in Hong Kong and formerly marketed in the United Kingdom and Ireland.
5.	Profeno	63	Name identified in RxNorm database. Per Redbook, product is deactivated and no generic equivalents are available.
6.	Pre Sed	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Predator	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Predyne	62	Veterinary product.
9.	Prondol	62	International product formerly marketed in the United Kingdom and Ireland.
10.	Prednesol	60	International product marketed in Ireland and in the United Kingdom.
11.	Prednoral	60	Name identified in RxNorm database. Per Clinical Pharmacology, product is deactivated and no generic equivalents are available.
12.	Prevail	60	Product is not a drug. It is a topical hand sanitizer.
13.	Pro Red	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
14.	Pro-Med	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Predair	59	Brand discontinued with no generic equivalents available. ANDA 088415 withdrawn FR effective 09/22/1993.
16.	Predate-50	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
17.	Predef	58	Veterinary product.
18.	(b) (4) ***	58	Proposed CBER proprietary name for BLA 125737 withdrawn by Applicant. BLA 125737 approved under the proprietary name Prehevbrio.
19.	Preven Ec	58	Name identified in RxNorm database. Per Redbook, product is deactivated and no generic equivalents are available.
20.	Prodine	58	Veterinary product.
21.	Peri-D.O.S.	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
22.	Prodyne	57	Veterinary product.
23.	Profadol	57	Product is not a drug. It is an opioid analgesic developed in the 1960s but never approved or marketed.
24.	(b) (4)***	57	Proposed proprietary name for IND 137856 found unacceptable by DMEPA (OSE# 2020-1043779388). NDA 216264 approved under the proprietary name Bludigo.
25.	(b) (4)***	57	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (b) (4) due to confusion with a marketed product. Subsequently, the proposed proprietary name (b) (4)*** was found conditionally acceptable for IND (b) (4)
26.	Premique	56	International product marketed in the United Kingdom and Ireland.
27.	Premium	56	Veterinary product.
28.	Prepadine	56	International product marketed in the United Kingdom.
29.	Prepodyne	56	International drug product marketed in Canada.
30.	Previcox	56	Veterinary product.
31.	Prezatide	56	Product is not a drug. It is a tripeptide consisting of glycine, histidine, and lysine which readily forms a complex with copper ions.
32.	Privine	56	Name identified in RxNorm database. Per Redbook, product is deactivated and no generic equivalents are available.
33.	Pronto	56	This is not a drug. This is a spray used to kill household pests.
34.	Prostep	56	Brand discontinued with no generic equivalents available. NDA 019983 was withdrawn FR effective 06/18/2009.
35.	Brevidil	55	International product formerly marketed in United Kingdom.
36.	Pre Guard	55	Veterinary product.
37.	Prefrin	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
38.	Preludin	55	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 010460 and NDA 011752 withdrawn FR effective September 22, 1999.

No.	Name	POCA Score (%)	Failure preventions
39.	Puregon	55	International drug product marketed in several countries including Argentina, Australia, Austria, Belgium, Chile, China, and Czech Republic. International drug product formerly marketed in Finland and Norway.
40.	Ocu-Pred	52	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
41.	Pro Post 5000	47	Veterinary product.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion8F[e]

No.	Name	POCA Score (%)
1.	D & C Red No. 27	60
2.	D&C Red No. 21	60
3.	D&C Red No. 28	60
4.	D&C Red No. 30	60
5.	D&C Red No. 34	60
6.	D&C Red No. 6	60
7.	D&C Red No. 7	60
8.	D.C. Red No. 33	60
9.	D.C. Red No. 36	60
10.	Tri-Pseudo	60
11.	Tri-Sudo	60
12.	Hc Red No. 3	58
13.	Truvada	58
14.	Renovue-65	56
15.	Spravato	56
16.	Brivudine	55

[e] 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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DAMON A BIRKEMEIER
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VALERIE S VAUGHAN
11/08/2022 04:37:22 PM

MISHALE P MISTRY
11/08/2022 04:55:20 PM