CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209376Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	January 21, 2020
Application Type and Number:	NDA 209376
Product Name and Strength:	Tralement (trace element injection-4, USP) 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	American Regent
Panorama #:	2019-28889508-1
DMEPA Safety Evaluator:	Melina Fanari, R.Ph
DMEPA Team Leader:	Ashleigh Lowery, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tralement, which was found conditionally acceptable under NDA 209376 on April 15, 2019.[a] We internally initiated this review to capture additional names not previously identified in our previous review. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

2.1.1 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 262 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 20 names not previously analyzed. These names are included in Table 1 below.

2.1.2 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the 20 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%	20
Low similarity name pair: combined match percentage score ≤54%	0

[a] Griffis, M. Proprietary Name Review for Tralement (NDA 209376). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 April 15. Panorama No.: 2019-28889508.

[b] POCA search conducted on December 6, 2019 in version 4.3.

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

Our analysis of the 20 names contained in Table 1 determined none of the names will pose a risk for confusion with Tralement as described in Appendices C through H.

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, Tralement, is acceptable.

4 REFERENCE

1. *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.

APPENDICES

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-N/A

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:** Tralement **Dosage form:** injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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.	Tri Vent Hc	58	This name pair has sufficient orthographic and phonetic differences.
2.	Trelegy	56	This name pair has sufficient orthographic and phonetic differences.
3.	Triotann-S	56	This name pair has sufficient orthographic and phonetic differences.

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
4.	Triolein	61	Product is not a drug. It is a soap or detergent.

No.	Name	POCA Score (%)	Failure preventions
5.	Travogyn	58	International product formally marketed in Brazil.
6.	Trilocort	58	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
7.	Pro-Vent	57	International product formally marketed in the UK and Ireland.
8.	Tricetin	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
9.	Triclosept	56	International product formally marketed in the UK.
10.	Trisilane	56	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases.
11.	Trilaurin	55	Name identified in Rx Norm 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[c].-N/A

No.	Name	POCA Score (%)
12.	Pretomanid	59
13.	Predenema	58
14.	Qualitest	56
15.	Aprepitant	56
16.	Relebactam	56
17.	Balamine Dm	55
18.	Calabren	55
19.	Calamine	55
20.	Illuminet	55

[c] 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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELINA N FANARI
01/21/2020 09:40:06 AM

ASHLEIGH V LOWERY
01/21/2020 10:17:07 AM

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)

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Date of This Review:	April 15, 2019
Application Type and Number:	NDA 209376
Product Name and Strength:	Tralement (trace element injection-4, USP) 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	American Regent
Panorama #:	2019-28889508
DMEPA Safety Evaluator:	Melina Fanari, R.Ph
DMEPA Team Leader:	Sarah K. Vee, PharmD

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 25, 2019.

- Intended Pronunciation: Tra-le-ment
- Active Ingredient: trace element-4
- Indication of Use: As a source of zinc, copper, selenium and magnesium for total parental nutrition (TPN) when oral or enteral nutrition in not possible, insufficient or contraindicated.
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 3 mg/mL zinc sulfate, 0.3 mg/mL copper sulfate, 55 mcg/mL magnesium sulfate, 60 mcg/mL selenious acid
- Dose and Frequency: (b) (4) 1 mL added to TPN once daily
- How Supplied: 1 mL single-dose vials packaged in cartons containing 25 vials per carton
- Storage: Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature]

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tralement would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Gastroenterology and Inborn Errors Products (DGIEP) concurred with the findings of OPDP's assessment for Tralement.

2.2 SAFETY ASSESSMENT

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

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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

American Regent stated that the proposed proprietary name, Tralement, is a combination or blend of the words trace and element. 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 are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, February 20, 2019 e-mail, the Division of Gastroenterology and Inborn Errors Products (DGIEP) did not forward any comments or concerns relating to Tralement at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-five practitioners participated in DMEPA's prescription studies for Tralement. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 220 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, FDA Prescription Simulation Study, 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%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	207

[a] USAN stem search conducted on March 4, 2019.

[b] POCA search conducted on March 4, 2019 in version 4.3.

Low similarity name pair: combined match percentage score ≤54%	25

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

Our analysis of the 238 names contained in Table 1 determined none of the names will pose a risk for confusion with Tralement as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology and Inborn Errors Products (DGIEP) via e-mail on April 10, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Gastroenterology and Inborn Errors Products (DGIEP) on April 15, 2019, they stated no additional concerns with the proposed proprietary name, Tralement.

3 CONCLUSION

The proposed proprietary name, Tralement, is acceptable.

If you have any questions or need clarifications, please contact Shawnetta Jackson, OSE project manager, at 301-796-4952.

3.1 COMMENTS TO AMERICAN REGENT

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

If any of the proposed product characteristics as stated in your submission, received on January 25, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

[c] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

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***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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

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

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

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

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

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

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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.

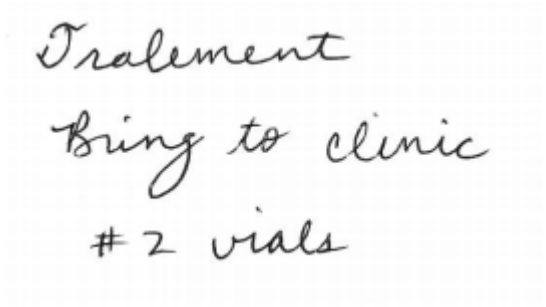
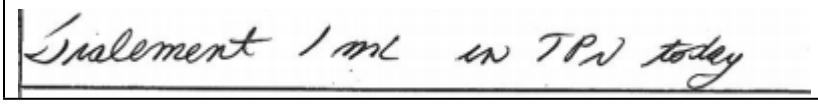
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Tralement Study (February 20, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Tralement Bring to clinic #2 vials
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

301People Received Study
95People Responded

Study Name: Tralement

Total	22	19	54	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
JIALEMENT	0	0	1	1
JISLEMENT	0	0	2	2
TIALEMENT	0	0	6	6
TISLEMENT	0	0	2	2
TRALAMENT	0	10	0	10
TRALEMENT	21	0	38	59
TRALEMENT 1 ML	0	0	1	1
TRALIMENT	1	0	0	1

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TRALLAMENT	0	1	0	1
TRIALEMENT	0	0	4	4
TRILAMENT	0	2	0	2
TROLAMENT	0	3	0	3
TROLIMENT	0	1	0	1
TROLLAMENT	0	1	0	1
TRYLAMINT	0	1	0	1

Reference ID: 4419589

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

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	**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.	Tralement	100	Name subject of this review
2.	Praluent	76	The ending sounds of the second syllable ('**le**' vs. '**lu**') and beginning 'm' sound in the third syllable of Tralement may provide some phonetic differences. The following differences in product characteristics help to mitigate the risk of errors: • Strength: Praluent is available in a 75 mg/mL or 150 mg/mL single dose pre-filled pen or syringe whereas Tralement is available in a single strength 1 mL multi-ingredient vial. A strength/dose must be included on a prescription for Praluent, and there is no overlap in strength/dose. • Dose/Frequency: The dose of Praluent is 75 mg or 150 mg every 2 weeks or 300 mg every 4 weeks whereas the dose of Tralement is (b) (4) 1 mL to be added to TPN once daily. There is no overlap in dose or frequency. • Tralement will be used as an additive in TPN solutions, which in clinical practice, is considered a high-alert medication requiring special safeguards in various points of the medication use process to reduce the risk of error. Additives for TPN solutions are typically ordered by the established name using a TPN prescription/ order program and it is not anticipated that Tralement will be written on a medication order alone. Additionally, there are compatibility considerations with TPN solutions.

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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.**
			Therefore, due to the above-mentioned factors we find this name pair acceptable.
3.	Galenamet	71	Foreign Product
4.	2,4,5-T-Trolamine	70	Name identified in RxNorm database. Unable to find product in commonly used drug databases.
5.	(b) (4) ***	70	(b) (4)

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	**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.**
			(b) (4) Therefore, due to the above-mentioned factors we find this name pair acceptable.
6.	Tri Levlen Deactivated according to RedBook; however generic equivalents available.	70	The ending sounds of the second syllable ('**le**' vs. '**lu**') and beginning 'm' sound in the third syllable of Tralement may provide some phonetic differences. The following differences in product characteristics help to mitigate the risk of errors: • Strength: Praluent is available in a 75 mg/mL or 150 mg/mL single dose pre-filled pen or syringe whereas Tralement is available in a single strength 1 mL multi-ingredient vial. A strength/dose must be included on a prescription for Praluent, and there is no overlap in strength/dose. • Dose/Frequency: The dose of Praluent is 75 mg or 150 mg every 2 weeks or 300 mg every 4 weeks whereas the dose of Tralement is (b) (4) 1 mL to be added to TPN once daily. There is no overlap in dose or frequency. • Tralement will be used as an additive in TPN solutions, which in clinical practice, is considered a high-alert medication requiring special safeguards in various points of the medication use process to reduce the risk of error. Additives for TPN solutions are typically ordered by the established name using a TPN prescription/ order program and it is not anticipated that Tralement will be written

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	**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.**
			on a medication order alone. Additionally, there are compatibility considerations with TPN solutions. Therefore, due to the above-mentioned factors we find this name pair acceptable.

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 (%)
7.	Tramacort	60
8.	Teramine	59
9.	Trilisate	59
10.	Trophamine 6%	59
11.	Trophamine 10%	59
12.	Ferralet 90	58
13.	Tagamet	58
14.	Tagamet 100	58
15.	Tolmetin	58
16.	Trialodine	58
17.	Trilafon	58
18.	Trilipix	58
19.	Termene	57
20.	Tranxene T-Tab	57
21.	Brilinta	57
22.	Trazodone	57
23.	Estraderm TTS 25	56
24.	Estraderm TTS 50	56
25.	Estraderm TTS 100	56
26.	Taladine	56
27.	Tranxene	56
28.	Treanda	56
29.	Trilostane	56
30.	Flovent	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:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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**
31.	Tri-Legest 21	68	This name pair has sufficient orthographic and phonetic differences.
32.	Aloemint	68	This name pair has sufficient orthographic and phonetic differences.
33.	Prevident	68	This name pair has sufficient orthographic and phonetic differences.
34.	Treximet	68	This name pair has sufficient orthographic and phonetic differences.
35.	Tranmep	65	This name pair has sufficient orthographic and phonetic differences.
36.	Tradjenta	65	This name pair has sufficient orthographic and phonetic differences.
37.	Tremin	65	This name pair has sufficient orthographic and phonetic differences.
38.	Trumenba	64	This name pair has sufficient orthographic and phonetic differences.
39.	Atrovent	62	This name pair has sufficient orthographic and phonetic differences.
40.	Neutracare Mint	62	This name pair has sufficient orthographic and phonetic differences.
41.	Trametinib	62	This name pair has sufficient orthographic and phonetic differences.
42.	Travatan Z	62	This name pair has sufficient orthographic and phonetic differences.
43.	Trulance	62	The ending sounds of the second syllable ('**le**' vs. '**lu**') and beginning 'm' sound in the third syllable of Tralement may provide some phonetic differences. The following differences in product characteristics help to mitigate the risk of errors:

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	**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**
			• Strength: Praluent is available in a 75 mg/mL or 150 mg/mL single dose pre-filled pen or syringe whereas Tralement is available in a single strength 1 mL multi-ingredient vial. A strength/dose must be included on a prescription for Praluent, and there is no overlap in strength/dose. • Dose/Frequency: The dose of Praluent is 75 mg or 150 mg every 2 weeks or 300 mg every 4 weeks whereas the dose of Tralement is (b) (4) 1 mL to be added to TPN once daily. There is no overlap in dose or frequency. • Tralement will be used as an additive in TPN solutions, which in clinical practice, is considered a high-alert medication requiring special safeguards in various points of the medication use process to reduce the risk of error. Additives for TPN solutions are typically ordered by the established name using a TPN prescription/ order program and it is not anticipated that Tralement will be written on a medication order alone. Additionally, there are compatibility considerations with TPN solutions. Therefore, due to the above-mentioned factors we find this name pair acceptable.
44.	Trav-L-Tabs	61	This name pair has sufficient orthographic and phonetic differences.
45.	Trazimera	60	This name pair has sufficient orthographic and phonetic differences.
46.	Trandate	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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**
47.	Triacetin	60	This name pair has sufficient orthographic and phonetic differences.
48.	Trianex	60	This name pair has sufficient orthographic and phonetic differences.
49.	Trileptal	60	This name pair has sufficient orthographic and phonetic differences.
50.	Acne Treatment	59	This name pair has sufficient orthographic and phonetic differences.
51.	Triamonide	59	This name pair has sufficient orthographic and phonetic differences.
52.	Triamonide 40	59	This name pair has sufficient orthographic and phonetic differences.
53.	Triesence	59	This name pair has sufficient orthographic and phonetic differences.
54.	Atralin	60	This name pair has sufficient orthographic and phonetic differences.
55.	Tragacanth	58	This name pair has sufficient orthographic and phonetic differences.
56.	Tranilast	58	This name pair has sufficient orthographic and phonetic differences.
57.	Travel-Ease	58	This name pair has sufficient orthographic and phonetic differences.
58.	Travel-Eze	58	This name pair has sufficient orthographic and phonetic differences.
59.	Trental	58	This name pair has sufficient orthographic and phonetic differences.
60.	Tretten	58	This name pair has sufficient orthographic and phonetic differences.
61.	Tri-Luma	58	This name pair has sufficient orthographic and phonetic differences.
62.	Tripelennamine	58	This name pair has sufficient orthographic and phonetic differences.
63.	Triple Paste	58	This name pair has sufficient orthographic and phonetic differences.
64.	Trisonex	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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**
65.	Taclonex	58	This name pair has sufficient orthographic and phonetic differences.
66.	Prolensa	57	This name pair has sufficient orthographic and phonetic differences.
67.	Duravent Pe	56	This name pair has sufficient orthographic and phonetic differences.
68.	Qternmet*** This is the root name for Qternmet XR*** which is an acceptable proposed proprietary name for pending NDA 210874 (RCM 2018-24782964; 10/19/2018).	56	This name pair has sufficient orthographic and phonetic differences.
69.	Mentadent	56	This name pair has sufficient orthographic and phonetic differences.
70.	Natural Dentist	56	This name pair has sufficient orthographic and phonetic differences.
71.	Reme-T	56	This name pair has sufficient orthographic and phonetic differences.
72.	Res-Q-Dent	56	This name pair has sufficient orthographic and phonetic differences.
73.	Talzenna	56	This name pair has sufficient orthographic and phonetic differences.
74.	Terminator	56	This name pair has sufficient orthographic and phonetic differences.
75.	Trabectedin	56	This name pair has sufficient orthographic and phonetic differences.
76.	Tetrasine Ex	56	This name pair has sufficient orthographic and phonetic differences.
77.	Tolnate	56	This name pair has sufficient orthographic and phonetic differences.
78.	Triamterene	56	This name pair has sufficient orthographic and phonetic differences.
79.	Triacet	56	This name pair has sufficient orthographic and phonetic differences.
80.	Trientine	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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**
81.	Tri-Legest Fe	56	This name pair has sufficient orthographic and phonetic differences.
82.	Presamine	56	This name pair has sufficient orthographic and phonetic differences.
83.	Tretin X	56	This name pair has sufficient orthographic and phonetic differences.
84.	Tronolane	57	This name pair has sufficient orthographic and phonetic differences.
85.	Trymex	57	This name pair has sufficient orthographic and phonetic differences.
86.	Triamcot	56	This name pair has sufficient orthographic and phonetic differences.
87.	Altretamine	56	This name pair has sufficient orthographic and phonetic differences.
88.	U-Tri-lone	56	This name pair has sufficient orthographic and phonetic differences.
89.	Triveen	55	This name pair has sufficient orthographic and phonetic differences.
90.	Avar-E Emollient	55	This name pair has sufficient orthographic and phonetic differences.
91.	Tretinoin	56	Orthographically, the suffixes of this name pair ('oin' vs 'ent') differ. The second ('ti' vs. 'le) and last syllables ('in' vs 'ment') provide some phonetic differences. Treinoin contains an extra syllable. The following differences in product characteristics help to mitigate the risk of errors: • Tralement will be used as an additive in TPN solutions, which in clinical practice, is considered a high-alert medication requiring special safeguards in various points of the medication use

No.	**Proposed name:** Tralement **Dosage form:** Injection **Strength(s):** 3 mg/mL zinc sulfate 0.3 mg/mL copper sulfate 55 mcg/mL magnesium sulfate 60 mcg/mL selenious acid **Usual Dose:** (b) (4) 1 mL added to TPN once daily	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**
			process to reduce the risk of error. Additives for TPN solutions are typically ordered by the established name using a TPN prescription/ order program and it is not anticipated that Tralement will be written on a medication order alone. Additionally, there are compatibility considerations with TPN solutions. • Dosage Form/Route of Administration: Tretinoin is available in multiple formulations topical cream, gel, solution and oral capsules. The dosage form would be specified for a prescription/ medication order of Tretinoin. Tralement is available as an injection added to TPN for intravenous administration and does not overlap with that of Tretinoin. Therefore, due to the above-mentioned factors we find this name pair acceptable.
92.	Triatex	55	This name pair has sufficient orthographic and phonetic differences.
93.	Theraplex T	55	This name pair has sufficient orthographic and phonetic differences.
94.	Alfenta	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 (%)
95.	Anzemet	54(O72)
96.	Dermakleen	54(O71)
97.	Ramelteon	54(O75)

No.	Name	POCA Score (%)
98.	Tracleer	54(O76)
99.	Trisoralen	54(O71)
100.	Aralen	53(O73)
101.	Atamet	53(O73)
102.	Tetradecene	53(O70)
103.	Allerest	52(O71)
104.	Metaraminol	52(O70)
105.	Multiple Trace Element	52(O74)
106.	Palm Kernelate	52(O73)
107.	Reliable Gentle	52(O72)
108.	Tiger Balm Liniment	52(O71)
109.	Transderm Nitro	52(O70)
110.	Transderm-Nitro	52(O70)
111.	Ultram ER	52(O74)
112.	Jet-Alert	51(O71)
113.	Balmex Ointment	50(O70)
114.	Altren	48(O73)
115.	Melitracen	48(O71)
116.	Remifentanil	48(O71)
117.	Ergotrate Maleate	47(O72)
118.	Morantel	47(O71)
119.	Triavil	44

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
120.	Trace Metal	69	Discontinued drug product with no available generics
121.	Ultralente	68	Discontinued drug product with no available generics
122.	Tormentil	64	Foreign Product
123.	Triaminic	64	Discontinued drug product with no available generics
124.	Triaminic-12	64	Discontinued drug product with no available generics
125.	Tornalate	63	Discontinued drug product with no available generics
126.	Racementhol	62	Name identified in RxNorm database. Unable to find product in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
127.	Serevent	62	Discontinued drug product with no available generics
128.	Tri-Tannate	62	Discontinued drug product with no available generics
129.	(b) (4) ***	62	Proposed proprietary name for CBER IND (b) (4) found to be unacceptable (b) (4) (initial denial) and (b) (4) (reconsideration denial)
130.	Radent	61	Foreign Product
131.	Salbuvent	61	Foreign Product
132.	Strazepam	61	Discontinued drug product with no available generics
133.	Travenol	61	Foreign Product
134.	Dura-Vent	60	Discontinued drug product with no available generics
135.	Alupent	60	Discontinued drug product with no available generics
136.	Talacen	60	Discontinued drug product with no available generics
137.	Talpen	60	Foreign Product
138.	Tramake	60	Foreign Product
139.	Tresaderm	60	Veterinary Product
140.	Triclonex	60	Name identified in RxNorm database. Unable to find product in commonly used drug databases
141.	Trilone	60	Discontinued drug product with no available generics
142.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) found unacceptable (OSE (b) (4)); subsequent name (b) (4) *** found unacceptable (OSE (b) (4)). No additional names have been submitted for this application.
143.	Dura-VentA	58	Discontinued drug product with no available generics
144.	Ferralet	58	Discontinued drug product with no available generics
145.	Ferralet Td	58	Discontinued drug product with no available generics
146.	Poly-Vent	58	Discontinued drug product with no available generics
147.	Nitrazepam	58	Foreign Product
148.	Tetrazepam	58	Foreign Product

No.	Name	POCA Score (%)	Failure preventions
149.	Tetramed	58	Discontinued drug product with no available generics
150.	Threamine	58	Discontinued drug product with no available generics
151.	Threonate	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
152.	Tramalgin	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
153.	Treagan	58	Discontinued drug product with no available generics
154.	Trilinolenin	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
155.	Tripalmitin	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
156.	Epridient	58	Name identified in RxNorm database. Unable to find product in commonly used drug databases
157.	Valertest	57	Foreign Product
158.	Triazulenone	57	Name identified in RxNorm database. Unable to find product in commonly used drug databases
159.	Allent	57	Discontinued drug product with no available generics
160.	Arbralene	57	Foreign Product
161.	Leventa	57	Name identified in RxNorm database. Unable to find product in commonly used drug databases
162.	Oradent	57	Name identified in RxNorm database. Unable to find product in commonly used drug databases
163.	Tobralex	57	Foreign Product
164.	Triazulenone	57	Name identified in RxNorm database. Unable to find product in commonly used drug databases
165.	Tranxene-SD	57	Discontinued drug product with no available generics
166.	Tyramine	57	Discontinued drug product with no available generics
167.	(b) (4) ***	56	Withdrawn proposed proprietary name for ANDA (b) (4)
168.	Betavent	56	Discontinued drug product with no available generics
169.	Orlenta	56	Discontinued drug product with no available generics
170.	Pralmorelin	56	Veterinary Product
171.	Tadenan	56	Foreign Product
172.	Tiletamine	56	Foreign Product

No.	Name	POCA Score (%)	Failure preventions
173.	Terra-Vet	56	Veterinary Product
174.	Tramake Insts	56	Foreign Product
175.	Trehalose	56	Discontinued drug product with no available generics
176.	Timentin	56	Discontinued drug product with no available generics
177.	Trilinolein	56	Name identified in RxNorm database. Unable to find product in commonly used drug databases
178.	Trilitron	56	Discontinued drug product with no available generics
179.	Trionate	56	Discontinued drug product with no available generics
180.	Trinalin	56	Discontinued drug product with no available generics
181.	Trynate	56	Name identified in RxNorm database. Unable to find product in commonly used drug databases
182.	Beclovent	56	Discontinued drug product with no available generics
183.	Duralutin	56	Discontinued drug product with no available generics
184.	Pyrilamine	56	Discontinued drug product with no available generics
185.	Respivent	56	Discontinued drug product with no available generics
186.	Duranest	55	Discontinued drug product with no available generics
187.	Tri-Med	55	Discontinued drug product with no available generics

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

No.	Name	POCA Score (%)
188.	Prandimet	65
189.	Freshmint	64
190.	2,4-D-Trolamine	63

[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

Reference ID: 4419589

No.	Name	POCA Score (%)
191.	Amilamont	62
192.	Reglan ODT	62
193.	Chloramine-T	60
194.	Prolintane	60
195.	Breezee Mist	60
196.	Driminate	60
197.	Perox-A-Mint	60
198.	Saline Mist	60
199.	Di-Gel Mint	59
200.	Protamines	59
201.	Bromanate	58
202.	Feen-A-Mint	58
203.	Galliprant	58
204.	Plasmanate	58
205.	Pramlintide	58
206.	Rembrandt	58
207.	Alka-Mints	58
208.	Carminate	58
209.	Etretinate	58
210.	Metreleptin	58
211.	Palmate	58
212.	Protenate	58
213.	Dalacin T	57
214.	Protamone	57
215.	Palmitate	57
216.	Vital-Benz	57
217.	Bellamine S	56
218.	Calomist	56
219.	Feldene Melt	56
220.	Prazepam	56
221.	Preven Ec	56
222.	Procalamine	56
223.	Racemistat	56
224.	(b) (4) ***	56
225.	Artrosamin	56
226.	Carrageenan	56
227.	Fortamet	56
228.	Prazolamine	56
229.	Procalamine	56
230.	Procalamine 3	56
231.	Quadramet	56
232.	Marine Mist	55
233.	Relafen	55

Reference ID: 4419589

No.	Name	POCA Score (%)
234.	Striant	55
235.	Kerledex	55
236.	Preludin	55
237.	Selamectin	55
238.	Styramate	55

Reference ID: 4419589

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/s/

MELINA N FANARI
04/15/2019 03:42:49 PM

MISHALE P MISTRY on behalf of SARAH K VEE
04/15/2019 04:04:37 PM