CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208745Orig1s000

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:	September 8, 2016
Application Type and Number:	NDA 208745
Product Name and Strength:	Trulance (plecanatide) Oral Tablets, 3 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Synergy Pharmaceuticals
Panorama #:	2016-2862855-1
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Trulance, based the revised strength and dose. The proposed proprietary name, Trulance, was found conditionally acceptable under IND (b) (4) and NDA 208745 on May 11, 2016.[a] We previously reviewed the product with (b) (4) dose of 3 mg (b) (4) taken once daily with or without food. During review of the application, the proposed strength is 3 mg and the proposed dose is 3 mg taken once daily with or without food.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in strength and dose. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The August 30, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

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 is acceptable from a promotional and safety perspective.

If you have any questions or need clarifications, please contact Ginneh Stowe, OSE project manager, at 301-796-4049.

[a] [Barlow, M]. Proprietary Name Review for [Trulance (NDA 208745 & IND (b) (4))]. Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); [2016 May 16]. Panorama No. [2016-2862855].

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MATTHEW J BARLOW
09/08/2016

MISHALE P MISTRY
09/08/2016

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)
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Date of This Review:	May 11, 2016
Application Type and Number:	IND 74883 & NDA 208745
Product Name and Strength:	Trulance (plecanatide) Oral Tablets 3 mg (b)(4)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Synergy Pharmaceuticals
Panorama #:	2015-2032572 & 2016-2862855
DMEPA Primary Reviewer:	Matthew Barlow, RN, BSN
DMEPA Team Leader (Acting):	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Trulance, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by (b) (4), for this product.

1.1 REGULATORY HISTORY

The Applicant submitted the proposed proprietary name, Trulance*** on November 18, 2015 under IND 74883, and on February 23, 2016 under NDA 208745.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 18, 2015 & February 23, 2016 proprietary name submission.

- Intended Pronunciation: troo' lans
- Active Ingredient: plecanatide
- Indication of Use: Chronic idiopathic constipation (CIC)
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 3 mg, (b) (4)
- Dose and Frequency: One tablet (3 mg (b) (4)) once daily
- How Supplied: Blister Packs or Bottles
- Storage: Store at room temperature. Keep in original container/packaging to protect from moisture. (if distributed in bottles: Do not remove the desiccant from inside the bottle)
- Container and Closure Systems: N/A

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

67 practitioners participated in DMEPA's prescription studies. 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.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 7, 2015 and March 2, 2016 e-mail, the Division of Gastroenterology & Inborn Error Products (DGIEP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation Study or by the (b) (4) external study.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	212
Low similarity name pair: combined match percentage score ≤49%	6

[1]USAN stem search conducted on November 23, 2015.

[2] POCA search conducted on November 23, 2015.

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

Our analysis of the 220 names contained in Table 1 determined that none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Gastroenterology & Inborn Error Products (DGIEP) via e-mail on May 6, 2016. At that time we also requested additional information or concerns that could inform our review. DGIEP did not state additional concerns with the proposed proprietary name.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Alek Winiarski, OSE project manager, at 301-796-5295.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 18, 2015 and February 23, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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. [3]

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

***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 medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% 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.

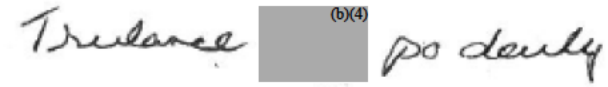
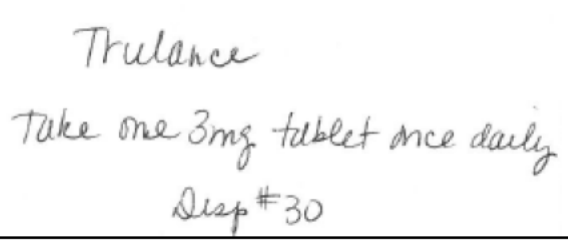
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤49%).

In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Trulance Study (Conducted on December 11, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Trulance 3 mg Take one tablet by mouth once daily Disp #30
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Trulance

Total	23	23	21	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
TRULAM	0	1	0	1
TRULANCE	22	15	21	58
TRULAND	0	1	0	1
TRULANTS	0	1	0	1
TRULANZE	0	1	0	1
TRULENCE	0	1	0	1
TRULENS	0	1	0	1
TRULENZE	0	1	0	1
TRULITZ	0	1	0	1
TULANCE	1	0	0	1

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

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg, (b)(4)** **Usual Dose: One tablet 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.	Trulance***	100%	This name is the subject of the review.
2.	(b)(4) ***	70%	This proposed proprietary name was found unacceptable by DMEPA (b)(4) The sponsor withdrew the application.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Trilyte	64%
2.	Trulicity	63%
3.	Tolinase	61%
4.	Radiance	61%
5.	Treanda	60%
6.	Dalvance	60%
7.	Ultra Balance	60%
8.	Ultrabalance	60%
9.	Trilisate	59%
10.	Triotann-S	59%
11.	Intelence	59%
12.	Triacin-C	58%
13.	Trianex	58%
14.	Triant-HC	58%
15.	Trumenba	58%
16.	Tru-micin	58%

No.	Name	POCA Score (%)
17.	Mitrolan	58%
18.	Rosula NS	58%
19.	Prolintane	58%
20.	Tri-Luma	57%
21.	Triple Dye	57%
22.	Trivase	57%
23.	Oro Cleanse	57%
24.	Trancot	56%
25.	Triacet	56%
26.	Tri Levlen	56%
27.	Tri-Linyah	56%
28.	Jardiance	56%
29.	Sunbalance	56%
30.	T-Tussin PE	56%
31.	Trintex	55%
32.	Talacen	54%
33.	Tranmep	54%
34.	Trelstar	54%
35.	Tridrane	54%
36.	Trinessa	54%
37.	Triple Paste	54%
38.	Tri-Tannate	54%
39.	Exuviance	54%
40.	Triban	53%
41.	Triblide	53%
42.	Trientine	53%
43.	Triglide	53%
44.	Trobicin	53%
45.	Tritan	53%
46.	Tretin X	52%

No.	Name	POCA Score (%)
47.	Tri Lo Mili	52%
48.	Tri-Legest	52%
49.	Tri-Legest 21	52%
50.	Tri-Lo-Mili	52%
51.	Trimo San	52%
52.	Tri-Pase	52%
53.	Tri Vent HC	52%
54.	Glucovance	52%
55.	Trental	51%
56.	Tronothane	51%
57.	Probalan	51%
58.	Spirulina	51%
59.	Triplex AD	51%
60.	Tencet	50%
61.	(b)(4) ***	50%
62.	Titralac	50%
63.	Tradjenta	50%
64.	Travatan	50%
65.	Travatan Z	50%
66.	Travenol	50%
67.	Trav-L-Tabs	50%
68.	Treagan	50%
69.	Triactin	50%
70.	Trialodine	50%
71.	Triatex	50%
72.	Tribulus	50%
73.	Tri-Legest FE	50%
74.	Triphasil-21	50%
75.	Triphasil-28	50%
76.	Truxazole	50%

No.	Name	POCA Score (%)
77.	Truxcillin	50%
78.	Trypan Blue	50%
79.	Tusscidin PE	50%
80.	Norplant	50%
81.	Oxy 10 Balance	50%
82.	Oxy Balance	50%

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg, (b)(4)** **Usual Dose: One tablet 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.	Prohance	69%	The prefix of this name pair has sufficient orthographic differences The first syllables of this name pair sound different.
2.	Triesence	68%	The infix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains an additional syllable.
3.	Prolensa	68%	The prefix of this name pair has sufficient orthographic differences. The first and last syllables of this name pair sound different. This name contains an additional syllable.
4.	Trilone	66%	The suffix of this name pair has sufficient orthographic differences. The last syllable of this name pair sound different.
5.	(b)(4) ***	64%	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair sounds different.
6.	Rebalance	64%	The prefix of this name pair has sufficient orthographic differences. The first/second syllable of this name pair sounds different. This name contains an additional syllable.

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg, (b)(4)** **Usual Dose: One tablet 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**
7.	U-Tri-Lone	64%	The prefix of this name pair has sufficient orthographic differences. This name contains an additional syllable. The first and last syllables of this name pair sound different.
8.	Trilafon	62%	The suffix of this name pair has sufficient orthographic differences. The first and last syllables of this name pair sound different. This name contains an additional syllable.
9.	Kliovance	62%	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains an additional syllable.
10.	Brilinta	60%	The prefix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains an additional syllable.
11.	Trovan IV	59%	The infix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
12.	Truvada	59%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg** (b)(4) **Usual Dose: One tablet 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**
13.	Ibrance	59%	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair sounds different.
14.	Tronolane	58%	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains an additional syllable.
15.	Truxade	58%	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different.
16.	Trandate	57%	The infix and suffix of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
17.	Triclonex	57%	The suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
18.	Tridane	57%	The suffix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
19.	Tranxene	56%	The infix of this name pair has sufficient orthographic differences. The second syllables of this name pair sound different.

No.	Proposed name: Trulance Established name: Plecanatide Dosage form: Oral Tablet Strength(s): 3 mg (b)(4) Usual Dose: One tablet 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
20.	Tri-Levlen	56%	The suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
21.	Triclosan	56%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllable of this name pair sound different. This name contains an additional syllable.
22.	Tussin PE	56%	The infix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains additional syllables.
23.	Triacin-C	56%	The infix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
24.	Triamcot	55%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
25.	Ellence	55%	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair sounds different.

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg, (b)(4)** **Usual Dose: One tablet 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**
26.	Telavancin	54%	The length of the names differs by 2 letters. The infix and suffix of this name pair have sufficient orthographic differences. The first and last syllables of this name pair sound different. This name contains additional syllables.
27.	Trandide	54%	The suffix of this name pair has sufficient orthographic differences. The second syllables of this name pair sound different.
28.	Trileptal	54%	The infix and suffix of this name pair has sufficient orthographic differences. The second/third syllable of this name pair sounds different. This name contains an additional syllable.
29.	Trokendi	54%	The suffix of this name pair has sufficient orthographic differences. The second/third syllable of this name pair sounds different. This name contains an additional syllable.
30.	Triaz Cleanser	53%	The infix and suffix of this name pair has sufficient orthographic differences. The first and second syllables of this name pair sound different. This name contains additional syllables.
31.	Trionate	53%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg** (b)(4) **Usual Dose: One tablet 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**
32.	Truphylline	53%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllable of this name pair sounds different. This name contains an additional syllable.
33.	Prulet	53%	The length of the names differs by 2 letters. The suffix of this name pair has sufficient orthographic difference. The second syllable of this name pair sounds different.
34.	Tirosint	52%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
35.	Triacin	52%	The infix and suffix of this name pair has sufficient orthographic differences. The second/third syllable of this name pair sounds different. This name contains an additional syllable.
36.	Triafed	52%	The suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
37.	Kepivance	52%	The prefix and infix of this name pair have sufficient orthographic differences. The first/second syllable of this name pair sounds different. This name contains an additional syllable.

No.	**Proposed name: Trulance** **Established name: Plecanatide** **Dosage form: Oral Tablet** **Strength(s): 3 mg, (b)(4)** **Usual Dose: One tablet 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**
38.	Multihance	52%	The prefix and infix of this name pair has sufficient orthographic differences. The first/second syllables of this name pair sound different. This name contains an additional syllable.
39.	Triam-A	52%	The infix and suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
40.	Trilog	51%	The suffix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different.
41.	Tolectin	50%	The suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains an additional syllable.
42.	Tolectin 600	50%	The suffix of this name pair has sufficient orthographic differences. The second/third syllables of this name pair sound different. This name contains additional syllables.
43.	Triam-Forte	50%	The infix and suffix of this name pair have sufficient orthographic differences. The second/third/fourth syllables of this name pair sound different. This name contains additional syllables.

No.	Proposed name: Trulance Established name: Plecanatide Dosage form: Oral Tablet Strength(s): 3 mg, (b)(4) Usual Dose: One tablet 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
44.	Trilocort	50%	The suffix of this name pair has sufficient orthographic differences. The second/third syllable of this name pair sounds different. This name contains an additional syllable.
45.	Besivance	50%	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllable of this name pair sounds different. This name contains an additional syllable.

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤49%)

No.	Name	POCA Score (%)
1.	Tri fed X	48%
2.	Vyvanse	48%
3.	Trusopt	46%
4.	Duratan PE	37%
5.	Invanz	28%
6.	Dents	20%

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.	[redacted]***	68%	This name was found unacceptable by DMEPA (OSE# 2012-1564). The application was approved under the proprietary name Triumeq.
2.	Balancer	59%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Trilostane	58%	Veterinary product.
4.	Trovan	58%	Brand discontinued with no generic equivalent available. NDA 020759 withdrawn FR effective 06/16/2006.
5.	Iotrolan	58%	Brand discontinued with no generic equivalent available. NDA 019580 withdrawn FR effective 06/10/1999.
6.	[redacted]***	56%	This name was found unacceptable by DMEPA [redacted] An alternate proposed proprietary name, [redacted] was found acceptable [redacted]).
7.	Trilocot	56%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Triolein	56%	Component of Lorenzo's oil.

No.	Name	POCA Score (%)	Failure preventions
9.	Tropolone	56%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Kepvance	56%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Travase	55%	Brand discontinued with no generic equivalent available. NDA 012828 withdrawn FR effective 08/19/2013.
12.	(b)(4)	55%	This is a secondary proposed proprietary name and the product was approved under proprietary name Trilipix.
13.	(b)(4)	54%	Proposed proprietary name found unacceptable by DMEPA (b)(4) Product approved under new proprietary name (b)(4)

No.	Name	POCA Score (%)	Failure preventions
14.	(b)(4)	54%	Proposed proprietary name was submitted for review, but was withdrawn by sponsor due to sponsor deciding not to market Lybrel generic. In another application, the proposed proprietary name was found unacceptable by DMEPA (OSE#2013-1487). The sponsor withdrew the name. and the product was approved under the proprietary name, Ibrance (OSE#2013-16612).
15.	Trilinolein	54%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Trilitron	54%	Brand discontinued with no generic equivalent available. ANDA 088515 & ANDA 088474 withdrawn FR effective 01/26/1990 & 02/02/2001.
17.	Trinalin	54%	Brand discontinued with no generic equivalent available. NDA 018506 withdrawn FR effective 04/04/2005.
18.	Trinza	54%	Modifier of the approved product, Invega Trinza
19.	Troclosene	54%	Veterinary Product.
20.	Chorulon	54%	Veterinary Product.
21.	Citrulline	54%	Product is not a drug. It is a compounding agent.

No.	Name	POCA Score (%)	Failure preventions
22.	Ferulate	54%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Surolan	54%	Veterinary Product.
24.	(b)(4)	53%	Proposed proprietary name withdrawn by sponsor (OSE# 2007-1308). Product approved under new proprietary name Fenoglide (OSE# 2007-1310).
25.	(b)(4)	53%	Proposed proprietary name withdrawn by sponsor (OSE# 2007-1308). Product approved under new proprietary name Fenoglide (OSE# 2007-1310).
26.	Trehalose	52%	Product is not a drug. It is a compounding agent.
27.	Brulidine	52%	International product marketed in Australia, New Zealand, Hong Kong, Ireland, UK, and Norway.
28.	Triclos	51%	Brand discontinued with no generic equivalent available. NDA 16809 & NDA 16830 withdrawn FR effective 11/05/1992.
29.	Trilaurin	51%	Triglyceride found in coconut oil.
30.	(b)(4)	51%	Proposed proprietary name found unacceptable by DMEPA (b)(4) . Alternate proposed proprietary name, (b)(4)

No.	Name	POCA Score (%)	Failure preventions
31.	Tru-Blu C-Hex 110	51%	Veterinary Product.
32.	Estroplan	51%	Veterinary Product.
33.	Tirilazad	50%	Investigational drug product.
34.	Tolazine	50%	Veterinary Product.
35.	Tranilast	50%	Product is not a drug. It is a compounding agent.
36.	[redacted] (b)(4)	50%	Proposed proprietary name for new dosage form of Treanda found unacceptable by DMEPA (OSE# 2013-693). DMEPA concluded new dosage form should be marketed under already marketed proprietary name, Treanda.
37.	Trenbolone	50%	Veterinary Product.
38.	[redacted] (b)(4) ***	50%	Proposed proprietary name was withdrawn by sponsor [redacted] (b)(4) Alternate proposed proprietary name, [redacted] (b)(4) ***, found acceptable [redacted] (b)(4). Application received Complete Response as of 11/4/2015.
39.	[redacted] (b)(4) ***	50%	Proposed proprietary name was withdrawn by sponsor [redacted] (b)(4) Alternate proposed proprietary name, [redacted] (b)(4) Application received a Complete Response as of 11/16/2015.

No.	Name	POCA Score (%)	Failure preventions
40.	Triazulenone	50%	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Trisiloxane	50%	Active ingredient in sunscreen (drometrizole trisiloxane) in international products.
42.	Tylan	50%	Veterinary Product.

Appendix H: Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	ULTRALENTE	62
2.	ORO CLENSE	60
3.	U-TRI-LONE	60
4.	PROLINTANE	58
5.	PRELONE	56
6.	PROLINE	56
7.	XTRA-LAX	56
8.	PROVENGE	55
9.	ATRALIN	54
10.	BROLENE	54
11.	NEUTRARINSE	54
12.	PRELUENT	54
13.	PROLEX	54
14.	PROLIXIN	54
15.	RELENZA	54
16.	PROLACTIN	53

No.	Name	POCA Score (%)
17.	PROLASTIN	53
18.	ATROVENT	52
19.	BROM TANN PE	52
20.	FLUORINSE	52
21.	LUTRELIN	52
22.	PRALUENT	52
23.	PRILOSEC	52
24.	PROZINC	52
25.	QUASENSE	52
26.	ROLAIDS	52
27.	STRIANT	52
28.	CTX3 RINSE	51
29.	CTX4 RINSE	51
30.	DROLBAN	51
31.	RELAXIN	51
32.	BRIAN CARE	50
33.	CAVIRINSE	50
34.	DRONCIT	50
35.	KERLONE	50
36.	PRASCEND	50
37.	PROCAN SR	50
38.	PROFLEX	50
39.	PROGLYCEM	50
40.	PROLEX D	50
41.	PURELAX	50
42.	Q-TUSSIN PE	50
43.	SULINDAC	50

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MATTHEW J BARLOW
05/11/2016

MISHALE P MISTRY
05/11/2016