

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208956Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review: November 10, 2016
Application Type and Number: NDA 208956
Product Name and Strength: Triptodur (triptorelin pamoate for (b) (4) suspension) for injection, 22.5 mg
Product Type: Single
Rx or OTC: Rx
Applicant/Sponsor Name: Arbor Pharmaceuticals, LLC
Panorama #: 2016-9931101
DMEPA Primary Reviewer: Sarah K. Vee, PharmD
DMEPA Team Leader (Acting): Hina Mehta, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Triptodur, 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 [REDACTED]^{(b) (4)} for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 30, 2016 proprietary name submission.

- Intended Pronunciation: TRIP-toe-der
- Active Ingredient: triptorelin pamoate
- Indication of Use: for the treatment of children with central precocious puberty
- Route of Administration: Intramuscular injection
- Dosage Form: for injection
- Strength: 22.5 mg
- Dose and Frequency: 22.5 mg once every 24 weeks
- How Supplied: single-dose vial, prefilled syringe with water for injection
- Storage: Store at 20-25°C (68-77°F) [see USP Controlled Room Temperature]. Do not freeze.

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 Metabolism and Endocrinology Products (DMEP) 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^a.

^a USAN stem search conducted on 9/13/2016.

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Triptodur, 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

Eighty-three 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, September 14, 2016 e-mail, the Division of Metabolism and Endocrinology Products (DMEP) 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 $\geq 50\%$ retrieved from our POCA search^b organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	127
Low similarity name pair: combined match percentage score $\leq 49\%$	1

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, Triptodur will be available in strength of 22.5 mg. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Triptodur that were not identified in POCA.

Table 1A. eDRLS Search Results ^c	POCA Score (%)
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^b POCA search conducted on 9/8/2016.

Temazepam	56
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2.2.7 Safety Analysis of Names with Potential Orthographic, Spelling, and Phonetic Similarities

Our analysis of the 130 names contained in Table 1 and Table 1A determined 130 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to DMEP via e-mail on November 1, 2016. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DMEP on November 10, 2016, they stated no additional concerns with the proposed proprietary name, Triptodur.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 30, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

^c eDRLS search conducted on (October 13, 2016).

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 support 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.^d

^d 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 $\geq 70\%$).

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
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common strength or dose.			
<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	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 $\geq 50\%$ to $\leq 69\%$).

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
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	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> • 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	<p>Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</p>

	<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • 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 <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

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. Triptodur Study (Conducted on 9/9/2016)

Handwritten Medication Order/Prescription	Verbal Prescription
<p>Medication Order:</p> <p><i>Triptodur 22.5mg intramuscular injection</i></p> <p><i>today</i></p>	<p>Triptodur Bring to office</p> <p>Disp: #1 kit</p>
<p>Outpatient Prescription:</p> <p><i>Triptodur</i></p> <p><i>Bring to office</i></p> <p><i># 1 kit</i></p>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Triptodur

309 People Received Study

83 People Responded

Total	29	21	33	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
JRIPTODUR	1	0	0	1
TRITODUR	0	0	1	1
TRIPADUX	0	0	1	1
TRIPDIDUR	0	1	0	1
TRIPDODUR	0	1	0	1
TRIPLE DUR	0	1	0	1
TRIPSDUR	1	0	0	1
TRIPTADAS	0	0	1	1
TRIPTADUR	0	0	9	9
TRIPTADURA	0	1	0	1
TRIPTADUS	0	0	4	4
TRIPTODA	0	1	0	1
TRIPTODERM	0	1	0	1
TRIPTODUR	27	11	9	47
TRIPTODURMG	0	0	1	1
TRIPTODUS	0	0	7	7

TRIPTUDER	0	1	0	1
TRITODUR	0	1	0	1
TRITUDER	0	1	0	1
TRYPTODUR	0	1	0	1

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

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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.	Triptodur***	100	Subject of this review.

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

No.	Name	POCA Score (%)
1.	Trecator	66
2.	Tribenzor	64
3.	Trituss ER	62
4.	Nitro-Dur	61
5.	Triposed	60
6.	Tricor	60
7.	Trital SR	59
8.	Depodur	58
9.	Testomar	58
10.	Theo-Dur	58
11.	Trapidil	58
12.	Tri-Sudo	58
13.	Rescriptor	56
14.	Tramadol ER	55
15.	Temodar	54
16.	Camptosar	52
17.	Thrombinar	52
18.	Trazodone	52
19.	Tribulus	52

No.	Name	POCA Score (%)
20.	Tricosal	52
21.	Trileptal	52
22.	(b) (4)	52
23.	Troxycya ER	52
24.	Triderm	51
25.	Triflusal	51
26.	Tipranavir	50
27.	Truxadryl	50

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

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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.	(b) (4)	66	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
2.	Tryptosom	66 (P70)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different. Additionally, both products have different setting of use. Triptodur would only be administered by a healthcare provider in an office setting whereas Tryptosom is an over the counter dietary supplement product. Therefore in this instance, given the differences, the risk of confusion is minimal.

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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
3.	Triptone	64 (P63)	<p>The prefixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different. Triptodur has an extra syllable.</p> <p>Additionally, both products have different setting of use. Triptodur would only be administered by a healthcare provider in an office setting whereas Triptone is an over the counter product. Therefore in this instance, given the differences, the risk of confusion is minimal.</p>
4.	Triptorelin	60	Established name of the proposed proprietary name.
5.	Tryptophan	61 (P67)	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The third syllables of this name pair sound different.</p> <p>Additionally, both products have different setting of use. Triptodur would only be administered by a healthcare provider in an office setting whereas Tryptophan is an over the counter dietary supplement product. Therefore in this instance, given the differences, the risk of confusion is minimal.</p>
6.	Trelstar	58	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Triptodur has an extra syllable.</p> <p>The strength is required to be specified for Trelstar.</p>
7.	Tri-Chlor	58	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Triptodur has an extra syllable.</p>

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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
8.	Tri-Statins	58	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
9.	Tripedia	57	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
10.	Temazepam	56	<p>The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Temazepam contains an extra syllable.</p>
11.	Triseptin	56	<p>The infixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
12.	Trizivir	56	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
13.	Triple Dye	55	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The second and third syllables of this name pair sound different.</p>
14.	Tristoject	54	<p>The suffixes of this name pair have sufficient orthographic differences.</p> <p>The first and third syllables of this name pair sound different.</p>

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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
15.	(b) (4)	52	<p>The prefixes and infixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different.</p>
16.	(b) (4)	52	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
17.	Tri-Kort	52	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first and second syllables of this name pair sound different. Triptodur has an extra syllable.</p>
18.	Triostat	52	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
19.	Trisenox	52	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
20.	Trivora	51	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
21.	Trivora-21	51	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Trivora-21 contains a modifier thus contains 3 extra syllables.</p>

No.	Proposed name: Triptodur Established name: triptorelin pamoate Dosage form: for injection Strength: 22.5 mg Usual Dose: 22.5 mg once every 24 weeks	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
22.	Trivora-28	51	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different. Trivora-28 contains a modifier thus contains 3 extra syllables.</p>
23.	Tramadol	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
24.	Treximet	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
25.	Triamcot	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
26.	Trientine	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>
27.	Tri-Vi-Sol	50	<p>The infixes and suffixes of this name pair have sufficient orthographic differences.</p> <p>The first, second, and third syllables of this name pair sound different.</p>

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

No.	Name	POCA Score (%)
1.	Imdur	46

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.	Triptifed	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
2.	Broncodur	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
3.	Tri-Pseudo	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
4.	Ketanodur	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
5.	Testoderm	60	Brand discontinued with no generic equivalent available. NDA 19762 withdrawn FR Effective 6/18/2009.
6.	Trasicor	60	Brand discontinued with no generic equivalent available. NDA 18166 withdrawn FR Effective 9/29/195.
7.	(b) (4)	59	Proposed proprietary name for ANDA 200494 withdrawn by the applicant on 2/7/2012
8.	(b) (4)	58	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
9.	Theodur***	58	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
10.	Triperidol	57	International product marketed in Belgium, UK and formerly marketed in France and Germany.
11.	(b) (4)	56	Proposed proprietary name for (b) (4) No Review was retrieved. (b) (4) approved for this NDA (pending).
12.	Tresaderm	56	Veterinary Product
13.	Tricodene	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)

No.	Name	POCA Score (%)	Failure preventions
14.	Tristearin	55	Product is not a drug. It is a hardening agent used in manufacturing.
15.	Streptodornase	54	Product is not a drug. It is an enzyme produce by bacteria.
16.	(b) (4)	54	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
17.	(b) (4)	54	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
18.	Trintex	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
19.	Triphed	54	Brand discontinued with no generic equivalent available. ANDA 88630 withdrawn FR effective 9/1/1994.
20.	Triple Wormer	54	Veterinary Product
21.	Trisofed***	54	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
22.	Tritop	54	Veterinary Product
23.	Curatoderm	53	International product marketed in Germany, Israel, Belgium, Poland, Spain, Switzerland, and UK.
24.	Triactin	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
25.	Triactin Dm	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
26.	Triacort	52	Brand discontinued with no generic equivalent available. ANDA 87113 withdrawn FR effective 5/23/1994.
27.	Trihist-D	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
28.	Trikof D	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
29.	(b) (4)	52	Proposed proprietary name withdrawn by the Applicant. Tri-Estarylla*** found acceptable for this ANDA 90793.

No.	Name	POCA Score (%)	Failure preventions
30.	Triphenicol	52	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
31.	Terfenor	50	International product marketed in UK and South Africa.
32.	Toposar	50	Brand discontinued with no generic equivalent available. ANDA 74166 withdrawn FR effective 11/17/2004.
33.	Tramacort***	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
34.	Trancopal	50	Brand discontinued with no generic equivalent available. NDA 11467 withdrawn FR effective 3/13/2009.
35.	Triclofos	50	Brand discontinued with no generic equivalent available. NDA 16809 & 16830 withdrawn FR effective 11/5/1992.
36.	Trihist Dm	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
37.	Trimpex	50	Brand discontinued with no generic equivalent available. NDA 17952 withdrawn FR effective 6/4/2004.
38.	Trimpex 200	50	Brand discontinued with no generic equivalent available. NDA 17952 withdrawn FR effective 6/4/2004.
39.	Trispec Dex***	50	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
40.	Tri-Tannate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
41.	Truxazole	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. (Deactivated according to Redbook)
42.	Trypsin	50	Product is not a drug. It is an enzyme produced by the pancreas used in research or in food processing.

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

No.	Name	POCA Score (%)
1.	(b) (4)	58
2.	Kraftnadd-Gr	57
3.	Crestor	56
4.	Predator	56
5.	Ritonavir	56
6.	Ceftiofur	54
7.	Proctocort	54
8.	Retadolor	54
9.	Prostin Vr	53
10.	Aristocort	52
11.	Chromonar	52
12.	Primacor	52
13.	Procto-Med	52
14.	Proctosol	52
15.	Practolol	51
16.	Profender	51
17.	Ramodar	51
18.	Aristocort R	50
19.	Brexidol	50
20.	Drixomed	50
21.	Drixoral	50
22.	Kraftobese Gr	50
23.	(b) (4)	50
24.	Lipitor	50
25.	Nutrestore	50
26.	Predcor	50
27.	Prepidil	50
28.	Prioderm	50
29.	Rifater	50
30.	Streptase	50

No.	Name	POCA Score (%)
31.	Vistogard	50
32.	Zerit XR	50

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Acence Tea Tree Tock Blemish Spot
2.	Acitretin
3.	Badger Sport SPF 35 Sunscreen
4.	Badger SPF 35 All Season Face
5.	All Natural
6.	Otrexup
7.	Selenium Sulfide
8.	Toasted Vanilla Sugar Hand Sanitizer
9.	Enchanted Forest Hand Sanitizer
10.	Fresh Cucumber Melon
11.	Joints And Muscles Pain Relieving
12.	Restoril
13.	Rasuvo

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

/s/

SARAH K VEE
11/10/2016

HINA S MEHTA
11/14/2016