

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
207621Orig1s000

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:	March 9, 2015
Application Type and Number:	NDA 207621
Product Name and Strength:	Troxyca ER (oxycodone hydrochloride and naltrexone hydrochloride) Extended-release capsules 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg
Product Type:	Multi-Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer Inc.
Submission Date:	December 22, 2014
Panorama #:	2014-46341
DMEPA Primary Reviewer:	James Schlick, MBA, RPh
DMEPA Acting Team Leader:	Vicky Borders-Hemphill, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Troxyca ER, 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 did not submit an external name study for this proposed proprietary name. We previously found the proposed proprietary name, Troxyca ER, acceptable in OSE review# 2013-414 and 2013-1855.

1.1 PRODUCT INFORMATION

The following product information is provided in the December 22, 2014 proprietary name submission.

- Intended Pronunciation: “TROKS’ ih-ka ee’ ahr”.
- Active Ingredient: oxycodone hydrochloride and naltrexone hydrochloride
- Indication of Use: management of moderate to severe pain when a continuous, around-the-clock Opioid analgesic is needed for an extended period of time
- Route of Administration: oral
- Dosage Form: extended-release capsules
- Strength: (oxycodone/naltrexone) 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg
- Dose and Frequency: 20 mg to 160 mg per day in two divided doses every 12 hours. Swallowed whole or the contents of the capsules sprinkled on apple sauce
- How Supplied: each strength in bottles of 100 capsules
- Storage: 25°C (77°F), with excursions permitted to 15 to 30°C (59-86°F)
- Container and Closure Systems: high density polyethylene (HDPE) bottles with (b) (4) child resistant screw cap

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

1.2 MISBRANDING ASSESSMENT

At the beginning of this review, The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) concurred with the findings of OPDP’s assessment of the proposed name.

At the midpoint of this review we received an additional comment from the Controlled Substance Staff (CSS) that stated the following:

(b) (4)

We provided this information to OPDP and they still maintain their non-objection to the name from a misbranding perspective in an email dated February 25, 2015. DMEPA and DAAAP concur with OPDP's assessment.

1.3 SAFETY ASSESSMENT

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

1.3.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary name¹.

1.3.2 *Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Troxyca ER, in their submission. This proprietary name is comprised of two components: 1) the proposed root name, Troxyca, and 2) a modifier, ER. The modifier 'ER' has been added to the proprietary name to highlight the extended release properties of the proposed drug product. We evaluate this modifier in section 2.2.6. The root name, Troxyca, contains a portion of the established name oxycodone ("oxy"). However, this constitutes less than half of the proposed proprietary name, Troxyca ER, and the placement of the letters "oxy" in the infix of the name do not represent a component of the name that is misleading or can contribute to medication error

1.3.3 *FDA Name Simulation Studies*

Ninety-five 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.

Forty-five out of ninety-five (47.3%) participants responded with the name 'Troxyca'. In the voice prescription study the letter string 'yca' was misinterpreted as the letter strings 'eca', 'eka', 'ica', and 'ika'. Also, the letter 'x' was misinterpreted as the letter string 'cs', 'ks', and 'qs'. In the outpatient and inpatient written prescriptions, participants misinterpreted the letter string 'yca' as 'yea'. Appendix B contains the results from the verbal and written prescription studies.

1.3.4 *Comments from Other Review Disciplines at Initial Review*

In response to the OSE, January 13, 2015 e-mail, the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

1.3.5 *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 search² organized as highly similar, moderately similar or low similarity for further evaluation

¹USAN stem search conducted on January 17, 2015.

² POCA search conducted on January 5, 2015.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	3
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	133
Low similarity name pair: combined match percentage score $\leq 49\%$	0

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

The proposed product, Troxyca ER, will be available in the following strengths:

- 10 mg/1.2 mg
- 20 mg/2.4 mg
- 30/3.6 mg
- 40/4.8 mg
- 60/7.2 mg
- 80 mg/9.6 mg

Since this is not a typical strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR^oPLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Troxyca ER that were not identified in POCA, and found to have an overlap in strength with Troxyca ER. Our search did not yield any potential names.

1.3.7 Evaluation of the Modifier ‘ER’

We requested the Applicant include a modifier to highlight the extended-release properties of the product.³ The applicant chose the modifier ER. According to ISMP’s List of Products with Drug Name Suffixes, the modifier “ER” has been used for other modified-release dosage formulations to distinguish the dosing schedule from currently marketed immediate release formulations, and has been used to signal “every 12 hour”, “twice daily”, “once daily”, and “three times daily” dosing schedules. This product is dosed every 12 hours; therefore, the use of the modifier “ER” is consistent with the dosing frequency associated with ER. We are not aware of any errors relating to misinterpretation of “ER”. Thus, we find the use of this modifier to be appropriate.

³ Memorandum of Teleconference for IND 107037, Troxyca (Oxycodone Hydrochloride/Naltrexone) Extended Release Capsules dated July 30, 2013. DARRTS Advice/ Information Request.

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

Our analysis of the 136 names contained in Table 1 determined 136 names will not pose a risk for confusion as described in Appendices C through H.

1.3.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Analgesia, Anesthesia, and Addiction Products (DAAAP) via e-mail on February 25, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Controlled Substance Staff (CSS) on February 25 2015, they provided the following comment which we evaluate in Section 1.2.

[REDACTED] (b) (4)

2 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Vaishali Jarral, OSE project manager, at 301-796-4248.

2.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 22, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

3 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.

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 DNCE. OPDP or DNCE 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 DNCE 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.⁴

⁴ National Coordinating Council for Medication Error Reporting and Prevention.
<http://www.nccmerp.org/about/MedErrors.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 do not share a 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 <i>z</i> and <i>f</i>), 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 as 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
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	<p>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.</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>

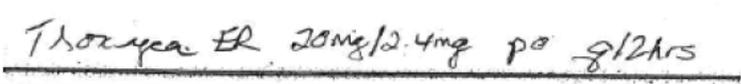
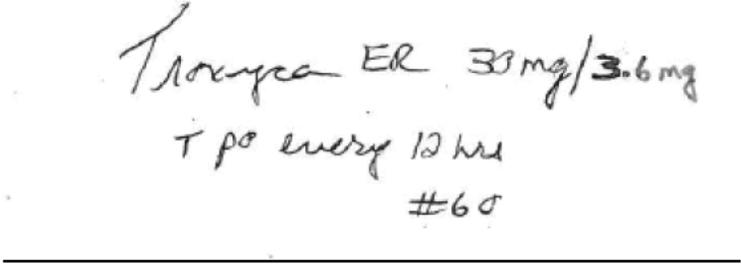
<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • 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. Troxyca ER Study (Conducted on January 14, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
<p><u>Medication Order:</u></p> 	<p>Troxyca ER 30 mg/3.6 mg Take 1 po every 12 hours Disp# 60</p>
<p><u>Outpatient Prescription:</u></p> 	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

253 People Received Study 95 People Responded				
Study Name: Troxyca ER				
Total	31	30	34	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
PERXICA ER 30/3.6MG	0	1	0	1
THOXYCEA	0	0	1	1
THOXYEA ER	0	0	1	1
TOXECA ER	0	1	0	1
TOXYCA ER	1	0	0	1
TRAFEXA ER	0	1	0	1
TRAXEQA ER	0	1	0	1
TREXASETA ER	0	1	0	1
TREXICA ER	0	1	0	1
TREXICAR ER	0	1	0	1
TRICIATE ER	0	1	0	1
TRIXEECA ER	0	1	0	1
TROCSECA ER	0	1	0	1
TROKSEKA ER	0	1	0	1
TRONYCA ER	0	0	2	2
TROQSECA ER	0	1	0	1
TROQSEKA ER	0	1	0	1
TROSICA ER	0	1	0	1
TROVYEA ER	1	0	0	1
TROXECA ER	0	3	0	3
TROXEKA ER	0	2	0	2
TROXFEA	0	0	1	1
TROXICA ER	0	1	0	1

TROXIKA ER	0	1	0	1
TROXSECAR	0	1	0	1
TROXSEEKA ER	0	1	0	1
TROXYCA	0	0	1	1
TROXYCA E R	0	0	1	1
TROXYCA ER	27	0	16	43
TROXYEA	0	0	1	1
TROXYEA ER	2	0	8	10
TROXYEA XR	0	0	1	1
TRUCKSEEKA ER	0	1	0	1
TRUCSEKA ER	0	1	0	1
TRUXECA ER	0	1	0	1
TRUXECA XR	0	1	0	1
TRUXEKA ER	0	1	0	1
TRUXICA ER	0	1	0	1
TSOXYCA ER	0	0	1	1
TURKSEKA ER	0	1	0	1

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

No.	<p>Proposed name: Troxyca ER Established name: oxycodone and naltrexone Dosage form: Extended-release capsule Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg Usual Dose: 10 mg to 80 mg every 12 hours</p>	<p>POCA Score (%)</p>	<p>Orthographic and/or phonetic differences in the names sufficient to prevent confusion</p> <p>Other prevention of failure mode expected to minimize the risk of confusion between these two names.</p>
1.	Trexima	73	Name not found in the commonly used databases.
2.	DroxIA	70	<p>The letter ‘y’ in Troxyca ER gives the name a shape different from that of Droxia. The letter ‘T’ in Troxyca does not look similar to the letter ‘D’ in Droxia</p> <p>The letter “c” located in front of the vowel provides for a hard “c” sound (“kuh”) in the Troxyca suffix vs. the letters “ia” (“ee-uh”) in Droxia suffix</p>
3.	droxicam	70	Name identified in RxNorm database. Unable to find product characteristics in internal databases.

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.	Proposed Name	POCA Score (%)
1.	Peroxin A	64
2.	Peroxin A 10	64
3.	Proxacol	63
4.	TriOxin	62
5.	Truxacaine	60
6.	TRECTOR	56
7.	Trixaicin	56
8.	Viroxyn	55
9.	Eltroxin	54
10.	Peroxyl	54
11.	TREXIMET	54
12.	Puroxcin	53
13.	Pyroxate	53
14.	Tricosal	53
15.	Trepoxen-250	52
16.	Triclosan	52
17.	TRIMOX	52
18.	Trintex	52
19.	Trioxsalen	52
20.	Tripedia	52
21.	troPICACYL	52
22.	Truxazole	52
23.	TREZIX	51
24.	Hydroxy-Cobal	50
25.	Proxigel	50
26.	Tetracap	50
27.	Thyrox	50
28.	TRANXENE	50

No.	Proposed Name	POCA Score (%)
29.	TRIACET	50
30.	Triacin C	50
31.	Triacting	50
32.	Triant-HC	50
33.	Trifed C	50
34.	TRILYTE	50
35.	(b) (4)***	50
36.	Triposed	50
37.	Trivora	50
38.	TRIVORA-21	50
39.	TRIVORA-28	50
40.	Truferic	50
41.	Truxcillin	50
42.	Truxicillin	50
43.	Zeroxin	50

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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: Troxyca ER Established name: oxycodone and naltrexone Dosage form: Extended-release capsule Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg Usual Dose: 10 mg to 80 mg every 12 hours	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.	PiroxicAM	64	The prefixes of this name pair have sufficient orthographic differences Piroxicam contains an extra syllable
2.	Doxy-Caps	59	The prefixes and suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
3.	DoxyCHEL	58	The prefixes and suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
4.	TrexALL	58	The suffixes of this name pair have sufficient orthographic differences Troxyca contains an extra syllable
5.	Droxidopa ^{***}	57	The suffixes of this name pair have sufficient orthographic differences Droxidopa ^{***} contains an extra syllable
6.	roxICET	57	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
7.	roxICET 5/500	57	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different

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No.	Proposed name: Troxyca ER Established name: oxycodone and naltrexone Dosage form: Extended-release capsule Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg Usual Dose: 10 mg to 80 mg every 12 hours	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.	Tresiba ^{***}	57	The infixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different
9.	Trihexy-2	57	The infixes and suffixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different
10.	FARXIGA	56	The infixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different
11.	TRASICOR	56	The infixes and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
12.	TRIOSTAT	56	The infixes and suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different

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No.	<p>Proposed name: Troxyca ER</p> <p>Established name: oxycodone and naltrexone</p> <p>Dosage form: Extended-release capsule</p> <p>Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg</p> <p>Usual Dose: 10 mg to 80 mg every 12 hours</p>	<p>POCA Score (%)</p>	<p>Prevention of Failure Mode</p> <p>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names</p>
13.	<p>(b) (4) ***</p>	54	(b) (4)
14.	TRUVADA	54	<p>The suffixes of this name pair have sufficient orthographic differences</p> <p>The first and second syllables of this name pair sound different</p>
15.	Triactin	53	<p>The infixes and suffixes of this name pair have sufficient orthographic differences</p> <p>The third syllables of this name pair sound different</p>
16.	Androxy	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.	TRITEC	52	<p>The infixes and suffixes of this name pair have sufficient orthographic differences</p> <p>Troxyca contains an extra syllable</p>

No.	Proposed name: Troxyca ER Established name: oxycodone and naltrexone Dosage form: Extended-release capsule Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg Usual Dose: 10 mg to 80 mg every 12 hours	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
18.	Trituss A	52	The infixes and suffixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different
19.	Aldroxicon	51	The prefixes of this name pair have sufficient orthographic differences Aldroxicon contains an extra syllable
20.	TOPOTECAN	51	The prefixes and infixes of this name pair have sufficient orthographic differences Topotecan contains an extra syllable
21.	Tri-Pseudo	51	The infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different
22.	troVAN	51	The suffixes of this name pair have sufficient orthographic differences Troxyca contains an extra syllable
23.	Truxadryl	51	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
24.	Trux-adryl	51	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
25.	NOroxIN	50	The prefixes and suffixes of this name pair have sufficient orthographic differences The first, second, and third syllables of this name pair sound different

No.	Proposed name: Troxyca ER Established name: oxycodone and naltrexone Dosage form: Extended-release capsule Strengths: 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, 80 mg/9.6 mg Usual Dose: 10 mg to 80 mg every 12 hours	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.	TARACTAN	50	The infixes and suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different
27.	(b) (4)***	50	(b) (4)
28.	TRADJENTA	50	The infixes and suffixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different
29.	TRIACIN-C	50	The infixes and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different
30.	TRICLOS	50	The suffixes of this name pair have sufficient orthographic differences Troxyca contains an extra syllable
31.	trocaine	50	The suffixes of this name pair have sufficient orthographic differences Troxyca contains an extra syllable
32.	trovan IV	50	The suffixes of this name pair have sufficient orthographic differences Troxyca contains an extra syllable

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

No.	Name	POCA Score (%)
1.	N/A	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
1.	Tetroxy	64	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
2.	Truxade	64	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
3.	tenoxicam	62	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
4.	Traxam	62	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
5.	(b) (4) ***	62	Name identified in DMEPA Proprietary Name Consultation Request database. Unable to find product characteristics in our internal databases.
6.	Seroxat	58	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
7.	Pur-oxy	57	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
8.	(b) (4) **	57	(b) (4)
9.	(b) (4) ***	57	

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No.	Name	POCA Score (%)	Failure preventions
10.	(b) (4) ***	56	Secondary name to Farxiga. Farxiga approved under NDA 202293 on January 8, 2014
11.	(b) (4) ***	56	Secondary name to Orbactiv. Orbactiv approved under NDA 206334 on August 6, 2014
12.	(b) (4) ***	56	Name found unacceptable by DMEPA (OSE# 2007-1571). Treximet approved under NDA 021926 on April 15, 2008
13.	oxy-CARE 502	55	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
14.	Tri-Otic	55	Veterinary Product
15.	troxerutin	55	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
16.	troBICIN	54	Product withdrawn from market and is available for veterinary use only. No available generics.
17.	trosyl	54	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
18.	Trifexis	52	Veterinary Product
19.	Triscon	52	Name identified in RxNorm database. The product characteristics were not found in commonly used databases.
20.	Zoxycil	52	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
21.	Perox-Aid	51	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
22.	(b) (4) **	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-1645). Product granted proprietary name Tri-Lo Marzia*** under ANDA 200541.
23.	Tri Lo Xerissa***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-1988). Product granted proprietary name Tri-Lo Rianra*** under pending application ANDA 203316.
24.	Tri-Lo-Xerissa***	51	Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2013-1988). Product granted proprietary name Tri-Lo Rianra*** under pending application ANDA 203316.
25.	Broxil	50	Name identified in RxNorm database. The product characteristics were not found in commonly used databases

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No.	Name	POCA Score (%)	Failure preventions
26.	oxymeta-12	50	Name identified in RxNorm database. The product characteristics were not found in commonly used databases
27.	(b) (4) ***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# 2011-261). Product granted proprietary name Tri-Estarylla under ANDA 090793 on January 30, 2013
28.	(b) (4) ***	50	Proposed proprietary name found unacceptable by DMEPA (OSE# 2012-309). Product granted proprietary name Trokendi XR under NDA 201635 on August 16, 2013

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

No.	Name	POCA Score (%)
1.	PROSCAR	57
2.	MYTREX A	56
3.	PROPECIA	56
4.	Brexin L.A.	54
5.	Photrex ^{***}	54
6.	OTREXUP	53
7.	(b) (4)***	52
8.	(b) (4)***	52
9.	Kronofed-A	52
10.	OXECTA	52
11.	(b) (4)***	52
12.	Droncit	51
13.	Loxicom	51
14.	PROTOPIC	51
15.	Brocadopa	50
16.	Brodspec	50
17.	CRIXIVAN	50
18.	Doxidan	50
19.	ETRAFON-A	50
20.	Flextra	50
21.	lornoxicam	50
22.	MELOXICAM	50
23.	Mitoxana	50
24.	PRADAXA	50
25.	PROCAPAN	50
26.	PROGLYCEM	50

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No.	Name	POCA Score (%)
27.	PROMACTA	50
28.	Propacet	50
29.	PROPACET 100	50
30.	Prostap 3	50

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/s/

JAMES H SCHLICK
03/09/2015

BRENDA V BORDERS-HEMPHILL
03/09/2015