CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208090Orig1s000

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:	January 28, 2015
Application Type and Number:	NDA 208090
Product Name and Strength:	Xtampza ER (oxycodone) Extended-release capsules 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg
Product Type:	Single
Rx or OTC:	Rx
Applicant/Sponsor Name:	Collegium Pharmaceutical
Submission Date:	December 17, 2014
Panorama #:	2014-45722
DMEPA Primary Reviewer:	James Schlick, MBA, RPh
DMEPA Acting Team Leader:	Vicky Borders-Hemphill, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xtampza 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 submitted an external name study, conducted by DSI, for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the December 17, 2014 proprietary name submission.

- Intended Pronunciation: ex tamp' zah ee ar
- Active Ingredient: Oxycodone
- Indication of Use: Management of pain severe enough to require daily, around-the-clock, long- term opioid treatment and for which alternative options are inadequate.
- Route of Administration: Oral
- Dosage Form: Extended-release capsules
- Strength: 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg
- Dose and Frequency: 9 mg to (b) (4) mg orally every 12 hours
- How Supplied/ Container and Closure: 100 count bottles
- Storage: Room temperature

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 Analgesia, Anesthesia, and Addiction Products (DAAAP) 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].

[1]USAN stem search conducted on December 19, 2014.

2.2.2 Components of the Proposed Proprietary Name

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

The Applicant also stated in their submission that the modifier "ER" is intended to convey the extended release properties of the product. Our evaluation of the modifier "ER" is described in Section 2.2.7

2.2.3 FDA Name Simulation Studies

Ninety-nine 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. In the voice prescription study, the most common misinterpretation was the omission of the letter 'p' and the misinterpretation of the letter 'm' for the letter 'n'. In the inpatient written prescription, the letter 'z' was misinterpreted as the letter 'r'. 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 29, 2014 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.

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 DSI.

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	39
Low similarity name pair: combined match percentage score ≤49%	2

[2] POCA search conducted on December 19, 2014.

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

The proposed product, Xtampza ER, will be available in strengths of 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg. Since this is not a commonly marketed strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Xtampza ER that were not identified in POCA, and found to have an overlap in strength with Xtampza ER. These names are evaluated in Appendix E.

Table 1A. (PR°PLLR™) **Search Results**	**POCA score**
Avinza	48
Tamiflu	48

2.2.7 FMEA of the Modifier 'ER'

During our initial review of the proposed proprietary name, Xtampza ER, we evaluated if this extended-release product required a modifier to convey the extended-release nature of the product.

First, we considered whether the lack of a modifier may actually contribute to practitioners' and patients' knowledge deficit about the extended-release properties of the drug products. As it relates to this product, this consideration led us to evaluate whether the addition of a modifier to the root name, Xtampza, might help to avoid some of the wrong technique and wrong frequency errors.

Next we evaluated the modifier with respect to wrong technique errors. We reviewed the Institute for Safe Medication Practices' (ISMP) list of "Oral Dosage Forms That Should Not Be Crushed" to identify if a modifier exists that could possibly convey that an extended-release dosage form should not be divided, cut, crushed, or chewed. We focused our review on those names with modifiers that are commonly used to denote extended-release (e.g. ER, SR, CR, XR, XL, LA,), since the Institute of Medicine has charged FDA and Industry to standardize abbreviations to the greatest extent possible. Our review found that this list contains a nearly equal number of extended-release drug products in which the proprietary name contains a modifier (n = 82) to extended-release products with drug names without modifiers (n = 84). Based on this information, we conclude that there is no standard single modifier currently on the market today that is definitively linked to the requirement that an extended-release product should not be manipulated prior to administration. Although a clear pattern did not emerge from our review of this list with modifiers, our medication error post-marketing experience with drug products marketed without a modifier in the proprietary name leads us to believe that the failure to include a modifier that conveys the extended-release properties of the drug may predispose the product to wrong technique and wrong frequency errors. Therefore, in some circumstances, a modifier in the proprietary name of an extended-release product may help reduce the risk of these types of error.

Finally, we evaluated the modifier to determine if it conveyed the extended-release dosing properties of the product. Currently there are several marketed extended-release products which use this modifier (e.g., Nucynta ER, Opana ER, VoSpire ER, Razadyne ER, Ultram ER, and Zohydro ER). The marketed names Opana ER, Nucynta ER, and Zohydro ER have the labeled meaning for extended-release. For these three names, the frequency of administration is twice daily, which is the same proposed frequency of administration for Xtampza ER. However, the modifier "ER" has not been exclusively used for products administered twice daily since there are examples of "ER" products that are administered at other frequencies (e.g., Razadyne ER and Ultram ER are administered once daily, Metadate ER is administered three times daily), Although this modifier cannot be consistently linked to a frequency of administration, the ER modifier has not been has not been cited as a contributing factor to wrong frequency errors in postmarketing reports.

Therefore, given the combination of factors considered above, we conclude that the proposed modifier, "ER", is appropriate for this product.

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

Our analysis of the 41 names contained in Table 1 determined 41 names will not pose a risk for confusion as described in Appendices C through H.

2.2.9 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 January 26, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on January 27, 2015, they stated no additional concerns with the proposed proprietary name, Xtampza ER.

3 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.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your December 17, 2014 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.

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. [3]

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

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

	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 do 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o 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.

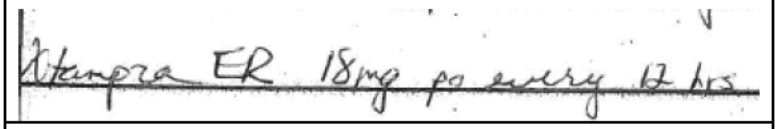
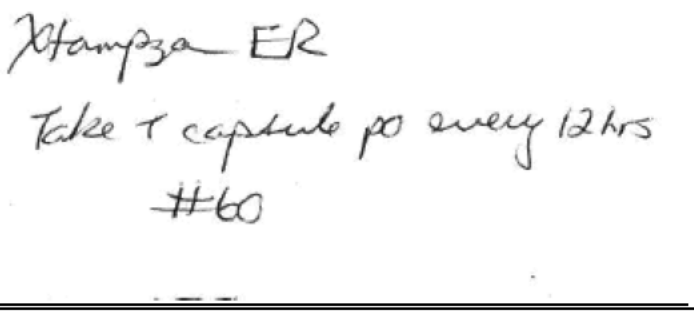
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Xtampza ER Study (Conducted on December 29, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Xtampza ER Take 1 capsule orally every 12 hours
Outpatient Prescription:  	Disp# 60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

252 People Received Study
99 People Responded

Study Name: Xtampza ER

Total	35	29	35	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
EXSEMZA ER	0	1	0	1
EXTAMSA ER	0	1	0	1
EXTAMZA ER	0	10	0	10
EXTANSA ER	0	1	0	1
EXTANZA ER	0	3	0	3
EXTEMZA ER	0	1	0	1
EXTENZA ER	0	1	0	1
EXTRAZA ER	0	1	0	1
HEXTAMZA ER	0	1	0	1
HEXTEMZA ER	0	1	0	1
HEXTIEMZA ER	0	1	0	1
ILLEGIBLE	1	0	0	1
NEXTAMZA ER	0	1	0	1
XITAMPRA ER	0	0	1	1
XITARPRA ER	0	0	1	1
XTAMA ER	0	1	0	1
XTAMPRA ER	0	0	21	21
XTAMPRA XR	0	0	1	1
XTAMPZA ER	34	0	1	35
XTAMSA ER	0	1	0	1
XTANPRA ER	0	0	6	6
XTANPZA ER	0	0	1	1
XTANSA ER	0	2	0	2
XTARIPRA ER	0	0	1	1

XTEMPRA ER	0	0	2	2
XTEMSAR ER	0	1	0	1
XTEMZA ER	0	1	0	1

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

No.	**Proposed name: Xtampza ER** **Established name: (oxycodone)** **Dosage form: Extended-release capsule** **Strength(s): 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg** **Usual Dose: 1 to 2 capsules every 12 hours**	**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.	N/A	N/A	

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.	Proposed Name	POCA Score (%)
1.	xtaNDI	58
2.	CampRAL	56
3.	VItamIN A	52
4.	Ixempra	57
5.	Kcentra	52
6.	Xtramins	51

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: Xtampza ER** **Established name: (oxycodone)** **Dosage form: Extended-release capsule** **Strength(s): 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg** **Usual Dose: 1 to 2 capsules 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.	Tempra	66	The prefixes of this name pair have sufficient orthographic differences Xtampza contains an extra syllable.
2.	Tempra 1	66	The prefixes of this name pair have sufficient orthographic differences Xtampza contains an extra syllable.
3.	Tempra 2	66	The prefixes of this name pair have sufficient orthographic differences Xtampza contains an extra syllable.
4.	Tempra 3	66	The prefixes of this name pair have sufficient orthographic differences Xtampza contains an extra syllable.
5.	ampYRA	52	The prefixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different
6.	J-Tan PD	64 (phonetic = 76)	The prefixes and suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different, and Xtampza contains an extra syllable.

No.	Proposed name: Xtampza ER Established name: (oxycodone) Dosage form: Extended-release capsule Strength(s): 9 mg, 13.5 mg, 18 mg, 27 mg, 36 mg Usual Dose: 1 to 2 capsules 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
7.	(b) (4) ***	55	The infixes and suffixes of this name pair have sufficient orthographic differences The second syllables of this name pair sound different, and Xtampza contains an extra syllable.
8.	STENDRA	54 (phonetic = 71)	The suffixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different, and Xtampza contains an extra syllable.
9.	Avinza	48	The prefixes and infixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different
10.	Tamiflu	48	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different

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

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

No.	Name	POCA Score (%)
1.	Xanax	46
2.	Xarelto	29

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.	(b) (4) ***	52	The name was found unacceptable in OSE Review# 2009-1763 on November 24, 2009. The name Ampyra was approved on January 22, 2010 under NDA 022250.
2.	Campto	50	Name identified in Rx Norm database. Unable to find product characteristics in commonly used drug databases

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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.	J-Tan D PD	56
3.	ZEMPLAR	54
4. .	Z-Xtra	54
5.	D-Tann CD	52
6.	D-Tann DM	52
7.	Duotan PD	52
8.	Dytan-CD	52
9.	Dytan-CS	52
10.	PENTASA	52
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