CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214826Orig1s000

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:	February 16, 202
Application Type and Number:	NDA 214826
Product Name and Strength:	Loreev XR (lorazepam) extended-release capsules, 1 mg, 2 mg, 3 mg (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Almatica Pharma, LLC (Almatica)
Panorama #:	2020-43970005
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
DMEPA Associate Director of Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Loreev XR***, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Almatica submitted an external name study, conducted by (b) (4), for this proposed proprietary name. We reviewed this study in our initial proprietary name review of Loreev XR under IND 117875.[a]

1.1 REGULATORY HISTORY

Edgemont Pharmaceuticals, LLC previously submitted the proposed proprietary name, Loreev XR*** on April 28, 2016 under IND 117875 and DMEPA found the name conditionally acceptable in OSE Review #2016-7736556, dated October 18, 2016.[b]

Subsequently, Almatica (change of sponsor) submitted the name, Loreev XR***, for review on November 18, 2020 under NDA 214826. We note that since our previous review of the name, (b) (4)

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 18, 2020.

- Intended Pronunciation: lor-EEV ECKS-AR
- Active Ingredient: lorazepam
- Indication of Use: (b) (4)
- Route of Administration: Oral
- Dosage Form: Extended-release capsules
- Strengths: 1 mg, 2 mg, 3 mg (b) (4)
- Dose and Frequency: (b) (4)

[a] Holmes, L. Proprietary Name Review for Loreev XR (IND 117875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Oct 18. Panorama No. 2016-7736556.

[b] Holmes, L. Proprietary Name Review for Loreev XR (IND 117875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Oct 18. Panorama No. 2016-7736556.

(b) (4)

- How Supplied: 30-count and 100-count bottles. Child-resistant closures.
- Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Keep bottles tightly closed.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Loreev XR*** would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Loreev XR***.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Loreev XR***.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The proposed proprietary name is comprised of two components: 1) the root name Loreev, and 2) the modifier, XR. Almatica indicated in their submission that the proposed proprietary name, Loreev XR***, is not derived from any one particular concept. Furthermore, Almatica indicated that the name contains the modifier XR to "*denote the extended-release formulation*" and that "*this modifier choice is consistent with the evolving FDA policy and a common modifier for extended-release products*." This name does not contain any components (i.e., route of administration, medical abbreviation, etc.) that are misleading or can contribute to medication error. An analysis of the appropriateness of the modifier is discussed in Section 2.2.4.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 1, 2020 e-mail, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Loreev XR*** at the initial phase of the review.

[c] USAN stem search conducted on January 22, 2021.

2.2.4 Safety Assessment of the Proposed Proprietary Name Loreev XR

In our previous proprietary name review of Loreev XR[d] under IND 117875, we considered the appropriateness of using the modifier "XR". We noted that the use of a modifier to convey that the product is an extended-release dosage form was contingent upon the product meeting the Agency's criteria for this designation. However, assuming those criteria are met, Almatica's intended meaning of the modifier was and continues to be consistent with the current use of the modifier in the marketplace. Therefore, we continue to find the use of the modifier "XR" appropriate for this product.

2.2.5 FDA Name Simulation Studies

Seventy-nine (79) practitioners participated in DMEPA's prescription studies for Loreev XR***. One respondent in the verbal study commented "*this could potentially be a LASA (look alike sound alike) drug name*" but did not state the name that Loreev XR was similar to. 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 prescription simulation studies.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

We conducted a POCA search of the root name, "Loreev" and the root name plus modifier, "Loreevxr". Our POCA search[e] identified a total of 122 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1, below. [f]

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the total number of names retrieved from our POCA search and (b) (4) external study. These names are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	103

[d] Holmes, L. Proprietary Name Review for Loreev XR (IND 117875). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 Oct 18. Panorama No. 2016-7736556.

[e] POCA search conducted on January 13, 2021 in version 4.4.

[f] The table includes names from both POCA searches. Duplicate names (retrieved in both searches) were counted once.

Low similarity name pair: combined match percentage score ≤54%	41

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

Our analysis of the 150 names contained in Table 1 determined none of the names will pose a risk for confusion with Loreev XR*** 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 Psychiatry (DP) via e-mail on February 11, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry (DP) on February 12, 2021, they stated no additional concerns with the proposed proprietary name, Loreev XR***.

3 CONCLUSION

The proposed proprietary name, Loreev XR***, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO ALMATICA PHARMA, LLC

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

If any of the proposed product characteristics as stated in your submission, received on November 18, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

3. ***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).

4. ***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).

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

APPENDICES

Appendix A

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

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

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www nccmerp.org/about-medication-errors Last accessed 10/05/2020.

Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 3-5) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.

- Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[h]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign 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.

Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated,

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

each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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

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

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

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

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

Table 3. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there	**Y/N**	Do the syllables have different phonologic processes, such

	a different number or placement of upstroke/downstroke letters present in the names?		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 ≥55% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.

<table>
<tr><td></td><td colspan="2">• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="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 <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>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?</td><td>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?</td></tr>
</table>

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Loreev XR* Study (Conducted on November 27, 2020)**

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Loreev XR 3mg po once daily	Loreev XR (b) (4) Take two capsules po once daily Dispense 60
Outpatient Prescription: Loreev XR (b) (4) ii caps po qd #60	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Loreev XR	

FDA Prescription Simulation Responses (Aggregate Report)

				209 People Received Study **79 People Responded**	
Study Name: Loreev XR					
Total	**18**	**21**	**12**	**28**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
LALIQUE XR	0	0	1	0	1
LOBIF XR	0	0	1	0	1
LOLIT XR	0	0	1	0	1
LOREB XR	0	0	1	0	1
LOREE XR	0	0	1	0	1
LOREEI XR	0	0	0	4	4
LOREEN XR	0	0	0	1	1
LOREER XR	0	0	0	5	5
LOREEU XR 3MG	0	0	0	1	1
LOREEV	1	0	0	1	2

LOREEV XR	17	21	0	15	53
LOREEV XR 3 MG	0	0	0	1	1
LOREV - XR	0	0	1	0	1
LORIB XR	0	0	2	0	2
MALEEB XR	0	0	1	0	1
MALIV XR	0	0	1	0	1
MOREN XL	0	0	1	0	1
NOREEB XR	0	0	1	0	1

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

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg (b) (4) **Usual Dose:** (b) (4)	**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.**
		POCA Search "Loreev"	**POCA Search "Loreevxr"**	
1.	Loreev XR***	69	100	This name (root name plus modifier) is the subject of this review.
2.	Loreev***	100	66	This is the root name of the proposed name Loreev XR*** which is the subject of this review.
3.	Loraz Loraz is a discontinued lorazepam tablet product. It was available in 0.5 mg, 1 mg, and 2 mg strengths. The ANDA for this product was withdrawn FR effective 06/05/1990. However, lorazepam generics are available.	80		Orthographically, the suffixes of the root name Loreev*** and the name Loraz look different ("-eev" vs. "-az"). Additionally, when written with a downstroke, the letter "z" further helps to differentiate the name pair. Phonetically, the second syllables of the root name Loreev*** and the name Loraz sound different (long "e" sound in "eev" vs. the short ă sound in "az"). The modifier "XR" in the proposed name helps to differentiate the names, if included.
4.	Loris	79		Orthographically, the suffixes of the root name Loreev*** and the name Loris have some orthographic differences ("ev" vs. "s"). Phonetically, the second syllables of the root name Loreev*** and

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg (b) (4) **Usual Dose:** (b) (4)	**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.**
		POCA Search "Loreev"	**POCA Search "Loreevxr"**	
				the name Loris sound different (long "e" sound in "eev" vs. the short ĭ sound in "is"). The modifier "XR" in the proposed name helps to differentiate the names, if included. Loris is a family tradename. The product line consists primarily of multiple antiseptic products with different ingredients (e.g., povidone iodine solution; povidone iodine and isopropyl alcohol applicators; and benzalkonium chloride swabs). Therefore, additional information is needed to inform the pharmacist of the desired product, which would help to mitigate name confusion. For these reasons, it is unlikely that confusion will occur between this name pair.
5.	Kloref	70		International product marketed in Greece.
6.	(b) (4) ***	70		(b) (4)

No.	Proposed name: Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg (b) (4) **Usual Dose:** (b) (4)	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.
		POCA Search "Loreev"	POCA Search "Loreevxr"	
				(b) (4)

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)	
		POCA Search "Loreev"	POCA Search "Loreevxr"
1.	Relovox		63
2.	Luvox CR		62
3.	Level	60	
4.	Florone	58	
5.	Florone E	58	
6.	Lorzone	58	46
7.	Zorvolex		58

No.	Name	POCA Score (%)	
		POCA Search "Loreev"	POCA Search "Loreevxr"
8.	Lodine XL		56
9.	Vaporex		55

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg, (b) (4) **Usual Dose:** (b) (4)	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**
		POCA Search "Loreev"	POCA Search "Loreevxr"	
1.	Lotrel	68	48	This name pair has sufficient orthographic and phonetic differences.
2.	Lorcet	66		This name pair has sufficient orthographic and phonetic differences.
3.	Dolorex	55	65	This name pair has sufficient orthographic and phonetic differences.
4.	Anorex-SR		62	This name pair has sufficient orthographic and phonetic differences.
5.	Laviv	62		Orthographically, the suffixes of the root name Loreev*** and the name Laviv look different due to the double letters "ee" in Loreev*** vs. the letter "i" in Laviv ("-eev" vs. "-viv") Phonetically, the first and second syllables of this name pair sound different due to the "lohr" vs. "lah" sound of the first syllables and the fact that the onsets for the second syllables start with different letters ("r" vs. "v").

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg, (b) (4) **Usual Dose:** (b) (4)	**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**
		POCA Search "Loreev"	**POCA Search "Loreevxr"**	
				The modifier "XR" helps to differentiate this name pair, if included. Laviv is an autologous cellular product indicated for improvement of the appearance of moderate to severe nasolabial fold wrinkles in adults. Administration of this product is limited to healthcare providers who have completed a Fibrocell-approved training program. Thus, the context of use for Laviv differs from that of Loreev XR*** which helps to minimize the potential for name confusion.
6.	Loryna	62	42	This name pair has sufficient orthographic and phonetic differences.
7.	Lotronex		62	This name pair has sufficient orthographic and phonetic differences.
8.	Altoprev	61		This name pair has sufficient orthographic and phonetic differences.
9.	Lortab 10	61		This name pair has sufficient orthographic and phonetic differences.
10.	Lortab	61	42	This name pair has sufficient orthographic and phonetic differences.
11.	Lovenox		61	This name pair has sufficient orthographic and phonetic differences.
12.	Klorvess	60		This name pair has sufficient orthographic and phonetic differences.
13.	Levoxyl		60	This name pair has sufficient orthographic and phonetic differences.
14.	Lortuss EX		60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg, (b) (4) **Usual Dose:** (b) (4)	**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**
		POCA Search "Loreev"	**POCA Search "Loreevxr"**	
15.	Lo/Ovral	59		This name pair has sufficient orthographic and phonetic differences.
16.	Lo/Ovral-28	59		This name pair has sufficient orthographic and phonetic differences.
17.	Lopressor		59	This name pair has sufficient orthographic and phonetic differences.
18.	Clorfed	58		This name pair has sufficient orthographic and phonetic differences.
19.	Levsinex SR		58	This name pair has sufficient orthographic and phonetic differences.
20.	(b) (4) ***		58	This name pair has sufficient orthographic and phonetic differences.
21.	Loprox		58	This name pair has sufficient orthographic and phonetic differences.
22.	Orlex		58	This name pair has sufficient orthographic and phonetic differences.
23.	Prorex		58	This name pair has sufficient orthographic and phonetic differences.
24.	Levo-T	57		This name pair has sufficient orthographic and phonetic differences.
25.	Larin 1.5/30	56		This name pair has sufficient orthographic and phonetic differences.
26.	Larin 1/20	56		This name pair has sufficient orthographic and phonetic differences.
27.	Lincorex		56	This name pair has sufficient orthographic and phonetic differences.
28.	Liotrix		56	This name pair has sufficient orthographic and phonetic differences.
29.	Lo-Trol	56		This name pair has sufficient orthographic and phonetic differences.
30.	Luride	56		This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Loreev XR **Established name:** lorazepam **Dosage form:** Extended-release capsules **Strengths:** 1 mg, 2 mg, 3 mg, (b) (4) **Usual Dose:** (b) (4)	**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**
		POCA Search "Loreev"	**POCA Search "Loreevxr"**	
31.	Recorlev***	56		This name pair has sufficient orthographic and phonetic differences.
32.	Valorin Extra		56	This name pair has sufficient orthographic and phonetic differences.
33.	Viorele	56	46	This name pair has sufficient orthographic and phonetic differences.
34.	(b) (4) ***	52		(b) (4)

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%)

No.	Name	POCA Score (%)	
		POCA Search "Loreev"	POCA Search "Loreevxr"
1.	Adderall XR		54
2.	Alora	54	
3.	Clarinex		54
4.	Levora	54	48
5.	Levora 0.15/30-21	54	48
6.	Levora 0.15/30-28	54	48
7.	Lo/Ovral Fe	54	
8.	Logen	54	
9.	Lorcet-HD	54	
10.	Nulev	54	
11.	Coreg CR		53
12.	Lotemax		53
13.	Uloric	53	
14.	Cerebyx		52
15.	Dolorex Forte		52
16.	Florinef	52	
17.	Cipro XR		50
18.	Ilevro	50	48
19.	Larin FE	50	
20.	Latrix		50
21.	Luvox		50
22.	Revalor		50
23.	Levoprome	49	
24.	Claris	48	
25.	Effexor XR		48
26.	Ilaris	48	
27.	Vpriv	48	
28.	Lorazepam	46	47
29.	Focalin XR		46
30.	Orajel Severe		46
31.	Revolt	46	
32.	Co-Lav	43	
33.	Loestrin Fe		41
34.	Loratadine	38	40
35.	Losartan	38	
36.	Abreva		30
37.	Cordran	26	
38.	Cozaar	22	

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
		POCA Search "Loreev"	POCA Search "Loreevxr"	
1.	Lodrane XR		68	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
2.	Zerit XR		64	Brand discontinued with no generic equivalents available. NDA 021453 withdrawn FR effective 07/21/2017.
3.	Norel EX		63	Name identified in RxNorm database. Product is discontinued and no generic equivalents identified.
4.	Lorexane	52	62	International product marketed in Australia.
5.	Orelvo***	62	49	Proposed proprietary name withdrawn by the Applicant. A new name, Lupkynis*** was found conditionally acceptable in OSE Review #2020-40685969 dated September 3, 2020.
6.	Lortab 0.5/33.3	61		The root name "Lortab" was identified in commonly used databases. However, this root name with the modifier "0.5/33.3", indicative of the strength was not found.
7.	Orelox		61	International product marketed in Germany, Brazil, France, and other foreign countries.
8.	Evorel 100	60		The root name, Evorel, is an international product marketed in Ireland, Israel, Mexico, and other foreign countries.
9.	Evorel 25	60		
10.	Evorel 50	60		
11.	Evorel 75	60		
12.	Kloref-S	60	56	International product formerly marketed in the United Kingdom.
13.	Levoxy		60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Lorelco	60	58	Brand discontinued with no generic equivalents available. NDA 017535 withdrawn FR effective 06/04/2004.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Loreev"	POCA Search "Loreevxr"	
15.	Lorsin	60		Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
16.	Revex		60	Brand discontinued with no generic equivalents available.
17.	Vortex		59	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
18.	Chlorex A		58	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
19.	Chlorex A12		58	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
20.	Hylorel	58		Brand discontinued with no generic equivalents available. NDA 018104 withdrawn FR effective 07/21/2017.
21.	Lopresor SR		58	International product marketed in Canada, Belgium, Italy, and other foreign countries.
22.	Lorabid	57		Brand discontinued with no generic equivalents available. NDA 050668 withdrawn FR effective 08/13/2018.
23.	Lorfan	57		Brand discontinued with no generic equivalents available. NDA 010423 withdrawn FR effective 09/17/2001.
24.	Loroxide		57	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
25.	Aloral	56		International product formerly marketed in the United Kingdom.
26.	Colrex		56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
27.	Laraflex		56	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Loreev"	POCA Search "Loreevxr"	
28.	Larin	56		Larin is the root name for a family of oral contraceptive products: Larin 1.5/30, Larin 1/20, Larin 24 Fe, Larin FE 1.5/30, Larin FE 1/20. There is no "Larin" product that does not have a modifier; thus, the modifier would have to be specified which would mitigate the potential for name confusion.
29.	Levall 2	56		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	Levall 5.0	56		Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
31.	Levall-12	56		Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
32.	Lodrane	56		Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
33.	Lodrane 24	56		Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
34.	Losec	56		The proprietary name Losec was changed to Prilosec in in the United States in 1990.
35.	Torem	56		International product formerly marketed in Germany and the Netherlands.
36.	(b) (4) ***		53	Proposed proprietary name for IND 124947 found unacceptable by DMEPA (OSE #2018-27985847 dated June 10, 2019). IND 124947 is pending and no new names have been submitted.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Loreev"	POCA Search "Loreevxr"	
37.	(b) (4) ***	52		Proposed proprietary name for IND 113924 found unacceptable by DMEPA (OSE #2018-20697570). NDA 211765 approved under new proprietary name Ubrelvy.

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

No.	Name	POCA Score (%)	
		POCA Search "Loreev"	POCA Search "Loreevxr"
1.	Brovex SR		66
2.	Belviq XR		60
3.	Brevoxyl		60
4.	Solurex		60
5.	Voltaren-XR		60
6.	Alrex		58
7.	Flarex	50	58
8.	Flo-Pred	58	
9.	Fluoridex		58
10.	Fluress	58	
11.	Verv	58	
12.	Fluorodex		57
13.	Forfivo XL		57
14.	Brovex D		56
15.	Dorflex		56
16.	Fluotrex		56
17.	Klotrix		56
18.	Pro Red	56	
19.	Relifex		56
20.	Xylarex		56
21.	Zervalx		56
22.	Aleve	55	34

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

No.	Name	POCA Score (%)	
		POCA Search "Loreev"	POCA Search "Loreevxr"
23.	Brovex		55
24.	Foleve	55	
25.	Roweepra XR		55
26.	Varivax		55

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