CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204417Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 16, 2018
Application Type and Number:	NDA 204417
Product Name and Strength:	Elepsia XR (levetiracetam) Extended-Release tablet 1,000 mg, 1,500 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sun Pharmaceutical Industries, Inc. (Sun Pharma)
Panorama #:	2018-25573385
DMEPA Safety Evaluator:	Chad Morris, PharmD, MPH
DMEPA Team Leader:	Lolita White, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Elepsia 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. Sun Pharma did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Sun Pharma previously submitted the proposed proprietary name, Elepsia XR, on December 2, 2016. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Elepsia XR, conditionally acceptable on February 21, 2017 (OSE Review #2016-11675000).[a] However, the application received a Complete Response on March 22, 2017.

Thus, Sun Pharma submitted the name, Elepsia XR, for review on August 30, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on August 30, 2018.

- Intended Pronunciation: E lep' see a ex are
- Active Ingredient: levetiracetam
- Indication of Use: Adjunctive therapy in the treatment of partial onset seizures in patients ≥ 12 years of age with epilepsy
- Route of Administration: oral
- Dosage Form: Extended-Release tablet
- Strength: 1,000 mg, 1,500 mg
- Dose and Frequency: Initiate with a dose of 1,000 mg once daily. The once daily dosage may be adjusted in increments of 1,000 mg every 2 weeks to a maximum recommended once daily dose of 3,000 mg.
- How Supplied: 30, 100, and 500-count bottles
- Storage: Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F) [see USP Controlled Room Temperature]. Dispense in tight, light-resistant container.
- Reference Listed Drug: Keppra XR (NDA 022285)

2 RESULTS

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

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[a]Morris, C. Proprietary Name Review for Elepsia XR (NDA 204417). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 FEB 21. Panorama No. 2016-11675000.

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Sun Pharma did not provide a derivation or intended meaning for the proposed proprietary name, Elepsia XR, in their submission. This proprietary name is comprised of a root name, Elepsia, and the modifier, 'XR'. The modifier 'XR' was assessed and found to be acceptable on December 9, 2014 in OSE Review #2014-38518.[c] We continue to agree with that assessment.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 20, 2018 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to Elepsia XR at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Forty-one practitioners participated in DMEPA's prescription studies for Elepsia XR. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 147 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name reviews. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous

[b] USAN stem search conducted on October 26, 2018.

[c] Harris, J. Proprietary Name Review for Elepsia XR NDA 204417. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 DEC 09. RCM No.: 2014-38518.

[d] POCA search conducted on October 25, 2018 in version 4.3.

review for the names evaluated previously. Therefore, we identified 16 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	15
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 16 names contained in Table 1 determined none of the names will pose a risk for confusion with Elepsia XR as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 14, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on November 16, 2018, they stated no additional concerns with the proposed proprietary name, Elepsia XR.

3 CONCLUSION

The proposed proprietary name, Elepsia XR, is acceptable.

If you have any questions or need clarifications, please contact Monique Killen, OSE project manager, at 240-402-1985.

3.1 COMMENTS TO SUN PHARMACEUTICAL INDUSTRIES, INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 30, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

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 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. [e]

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

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

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there 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 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[f]. 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.

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

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

   Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders, which are recorded electronically.

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

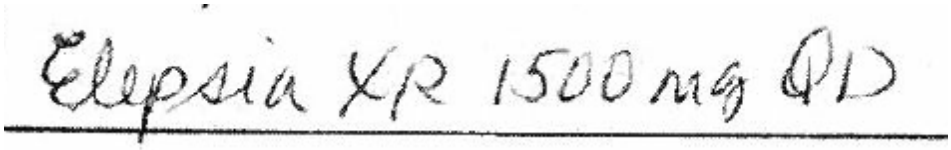
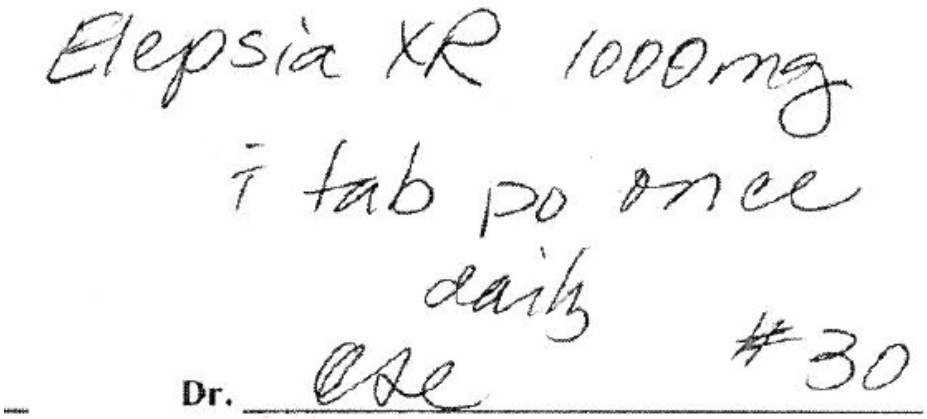
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤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. Elepsia XR Study (Conducted on September 21, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Elepsia XR 1000 mg 1 tab by mouth once daily #30
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Elepsia XR
As of Date 10/27/2018

306 People Received Study
41 People Responded

Study Name: Elepsia XR

Total	16	8	17	41
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ALEPSIA XR	0	2	0	2
ELEPSIA	0	0	1	1
ELEPSIA XR	16	3	15	44
ELIPSIA XR	0	0	1	1
ELLEPSIA XR	0	1	0	1
ILEPCIA XR	0	1	0	1
TELEPSIA XR	0	1	0	1

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

No.	**Proposed name:** Elepsia XR **Established name:** levetiracetam **Dosage form:** Extended-Release tablet **Strength(s):** 1,000 mg, 1,500 mg **Usual Dose:** 1,000 mg to 3,000 mg once daily	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	(b) (4) ***	71	(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 (%)
2.	(b) (4) ***	60

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:** Elepsia XR **Established name:** levetiracetam **Dosage form:** Extended-Release tablet **Strength(s):** 1,000 mg, 1,500 mg **Usual Dose:** 1,000 mg to 3,000 mg once daily	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
3.	Adhansia XR***	62	This name pair has sufficient orthographic and phonetic differences.
4.	Relexxii	60	This name pair has sufficient orthographic and phonetic differences.
5.	Serpasil	53	This name pair has sufficient orthographic and phonetic differences.
6.	Sensipar	52	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
	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
7.	Arelix	53	International product marketed in Japan, Brazil, Ireland, and South Africa; formerly marketed in Austria, Netherlands, UK, Germany, and Switzerland
8.	Epinal	46	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	(b) (4) ***	50	This is an alternate name for NDA 205029 approved under the established name.
10.	Episnap	48	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Paldesic	52	International product marketed in UK
12.	Pedesil	49	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
13.	Serpasil-Esidrix #1	49	Brand discontinued with no generic equivalents available. NDA 011878 withdrew FR effective 09/04/1996.
14.	Serpasil-Esidrix #2	49	Brand discontinued with no generic equivalents available. NDA 011878 withdrawn FR effective 09/04/1996.

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

No.	Name	POCA Score (%)
15.	Otezla Xr	58
16.	Talicia	56

[g] 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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JOHN C MORRIS
11/17/2018

LOLITA G WHITE
11/18/2018

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:	December 9, 2014
Application Type and Number:	NDA 204417
Product Name and Strength:	Elepsia XR*** (levetiracetam) Extended-Release Capsules 1000 mg and 1500 mg
Product Type:	Single Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	SPARC Ltd. (Sun Pharma Advanced Research Company Ltd.).
Submission Date:	September 30, 2014
Panorama #:	2014-38518
DMEPA Primary Reviewer:	Justine Harris, RPh
DMEPA Acting Team Leader/ Associate Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Elepsia XR, 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.

1.1 REGULATORY HISTORY

NDA 204417 is a 505(b)(2) application first submitted by Sun Pharma Global FZE on May 24, 2012 for the proposed new strengths of 1,000 mg and 1,500 mg for levetiracetam extended release tablets. This NDA application utilizes data from Keppra XR (NDA 022285). Keppra XR 500 mg was approved on September 12, 2008 and the 750 mg strength was approved on February 12, 2009. Sun developed higher strength tablets in order to reduce the number of tablets to be taken daily.

On December 26, 2012, Sun submitted the proposed proprietary name, (b) (4) but subsequently withdrew their request on March 8, 2013 and submitted a request for review of the alternate proposed proprietary name Elepsia XR. They submitted Elepsia XR after a teleconference with FDA where concerns with the proposed proprietary name (b) (4) (b) (4) were conveyed to Sun.

FDA issued a complete response letter to the applicant on March 29, 2013. Consequently, on April 4, 2013, Sun Pharma Global FZE withdrew their request for review of the proposed proprietary name Elepsia XR. This NDA application had a transfer of ownership from Sun Pharma Global FZE to SPARC Ltd. (Sun Pharma Advanced Research Company Ltd.). SPARC Ltd. submitted a request for proprietary name review of Elepsia XR on September 30, 2014.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 30, 2014 proprietary name submission.

- Intended Pronunciation: e lep′ see a ex are
- Active Ingredient: levetiracetam
- Indication of Use: : Indicated as adjunctive therapy in the treatment of partial onset seizures in patients ≥ 12 years of age with epilepsy
- Route of Administration: oral
- Dosage Form: tablet, Extended-Release
- Strength: 1000 mg and 1500 mg
- Dose and Frequency: Initiate with a dose of 1,000 mg once daily. The once daily dosage may be adjusted in increments of 1,000 mg every 2 weeks to a maximum recommended once daily dose of 3,000 mg.
- How Supplied: Both the 1,000 mg and 1500 mg tablets are supplied in bottles of 30, 100 and 500 tablets.

- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP Controlled Room Temperature]; Dispensed in tight, light-resistant container.
- Container and Closure Systems: The 30 count and 100 count bottles have child resistant caps; The 500 count bottles have non-child resistant cap.

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 Neurology Products (DNP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Elepsia XR in their submission. This proprietary name is comprised of a root name, Elepsia, and the modifier, 'XR'. The use of the modifier 'XR' is evaluated in Section 2.2.6.

2.2.4 FDA Name Simulation Studies

Ninety-eight practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products or any products in the pipeline.

Seventy- four participants (63 in the written prescription study and 11 in the verbal prescription study) interpreted the name correctly. Eleven participants in the verbal prescription study added an additional '-l-' in the name. Nine participants (4 in the verbal prescription study and 5 in the written prescription study) misinterpreted the letter '-e-' in the third position for the letter '-i-'. There was one case in the verbal prescription study where the modifier 'XR' was omitted and two cases (1 in the verbal study and 1 in the written study) where the modifier 'XR' was misinterpreted for 'SR'. Other

[1]USAN stem search conducted on October 10, 2014.

misinterpretations of the modifier 'XR' include 'EX' (1 in the verbal study) and 'XZR' (1 in the written prescription study). Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 22, 2014 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 Analysis of the Modifier 'XR'

There is currently no immediate release tablet marketed or proposed with only the root name "Elepsia"; however, there are other immediate release levetiracetam products on the market.

The modifier "XR" has been used for other dosage formulations dosed "every 12 hour" or "twice daily" or "once daily." In this case, Elepsia XR will be dosed once daily; therefore, the use of the modifier "XR" is consistent with the dosing frequency associated with other products that have an 'XR' modifier. In addition, the modifier 'XR' will help differentiate this extended-release formulation from the currently marketed immediate release formulations of levetiracetam. We recognize there are limitations to this approach since there is postmarketing evidence that modifiers have been omitted or overlooked; however, even if the modifier is omitted or overlooked, the order would need to be clarified with the prescriber or Elepsia XR would be dispensed. Therefore, given the totality of information considered, DMEPA concludes that the use of the modifier 'XR' for the proprietary name 'Elepsia XR' is appropriate.

2.2.6 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. POCA Search Results	**Number of Names**
Highly similar name pair: orthographic, phonetic or combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	91

[2] POCA search conducted on October 16, 2014.

Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 93 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on November 19, 2014. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on November 26, 2014, they stated no additional concerns with the proposed proprietary name, Elepsia XR.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796-0097.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 30, 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**

	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.

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

Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there medical and/or coined abbreviations in the proprietary name?**
	Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined

orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion, which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

Three separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity

in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders, which are recorded electronically.

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not

share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	**Y/N**	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if

	strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: 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. Elepsia XR Study (Conducted on October 20, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Elepsia XR 1000 mg po daily Outpatient Prescription: Elepsia XR 1500mg 1½ tabs po daily #60	Outpatient: Elepsia XR 1500 mg 2 tabs po daily #60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report) conducted October 20, 2014

259 People Received Study
108 People Responded

Study Name: Elepsia XR

Total	38	36	34	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ALEMSIA XR	0	1	0	1
ALEPSIA SR	0	1	0	1
ALEPSIA XR	0	1	0	1

ALIPSEA XR	0	1	0	1
ALLEPSIA XR	0	3	0	3
ELEPCESA	0	1	0	1
ELEPRIA XR	1	0	0	1
ELEPSIA EX	0	1	0	1
ELEPSIA SR	1	0	0	1
ELEPSIA XR	33	11	30	74
ELEPSIA XR 1500MG	0	1	0	1
ELEPSIA XZR	1	0	0	1
ELIPSEA XR	0	1	0	1
ELIPSIA XR	1	3	3	7
ELIPSIA XR 1000 MG	0	0	1	1
ELLEPSIA XR	0	7	0	7
ELLIPSIA XR	0	1	0	1
ELYSIA XR	1	0	0	1
HALEPSIA XR	0	1	0	1
HALIX XR	0	1	0	1
ILLIPSIA XR	0	1	0	1

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

No.	Proposed name: Elepsia XR Strength(s): 1000 mg and 1500 mg Usual Dose: 1,000 mg to 3,000 mg once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	ULESFIA	71	The suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, ('les' vs. ''lep' and "fee" vs. "see") There is no overlap in product characteristics. Ulesfia is a topical product used in the treatment of head lice.
2.	Deep Sea	70	The first and second syllables of this name pair sound different, and Elepsia contains 2 extra syllables. The prefixes of this name pair have sufficient orthographic differences. There is no overlap in product characteristics.

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.	CeleXA	64
2.	ELAPRASE	57
3.	eleLYSO	50
4.	eleSTAT	62
5.	eleSTRIN	54
6.	ELIPHOS	54
7.	ELLENCE	56
8.	EULEXIN	57
9.	EVISTA	53

10.	HepsERA	52
11.	ReleNZA	56
12.	VeleTRI	53
13.	ANEXsia	64
14.	ANEXsia 5/325	64
15.	ANEXsia 7.5/325	64
16.	ANEXsia 7.5/650	64
17.	Ereska***	55
18.	Essantia	55
19.	Sele-Pak	50

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

No.	**Proposed name: Elepsia XR** **Strength(s): 1000 mg and 1500 mg** **Usual Dose: 1,000 mg to 3,000 mg once daily**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	OlepTRO	56	The suffixes of this name pair have sufficient orthographic differences The first and third syllables of this name pair sound different and Elepsia contains one extra syllable.
2.	Eloctate	50	The infixes and suffixes of this name pair have sufficient orthographic differences The second and third syllables of this name pair sound different, and Elepsia name contains an extra syllable.
3.	(b) (4) ***	56	(b) (4)
4.	Glassia	54	The prefixes and infixes of this name pair have sufficient orthographic differences The first syllables of this name pair sound different, and Elepsia name contains an extra syllable.
5.	(b) (4) *** Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4))	56	(b) (4)

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

No.	Name	POCA Score (%)
1.	N/A	
2.		
3.		
4.		

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.	Alyfteo	53	Name identified in names entered by SE database. Unable to find product characteristics in internal databases.
2.	Antepsin	50	Foreign Drug
3.	Asepso	54	Name identified in RxNorm database. Unable to find product characteristics in internal databases.
4.	Elantan	50	Foreign Drug
5.	(b) (4) ***	50	Proposed Proprietary Name found unacceptable by DMEPA (OSE# (b) (4) (b) (4)). Product approved under new proprietary name (b) (4).
6.	(b) (4) ***	58	Proposed Proprietary Name found acceptable by DMEPA (OSE# (b) (4)); Application inactive
7.	Elixiral	53	Deactivated per redbook; no generics found
8.	(b) (4) ***	56	Applicant withdrew request

			for tradename review and did not submit alternate name
9.	(b) (4) ***	66	Name not reviewed; record closed
10.	leptin	56	Name identified in RxNorm Unable to find product characteristics in internal databases.
11.	Pepsin A	56	Name identified in RxNorm Unable to find product characteristics in internal databases.

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

No.	Name	POCA Score (%)
1.	alazmia	58
2.	ALBENZA	52
3.	Aldex AN	50
4.	aldioxa	52
5.	Alecensa	56
6.	Alera	52
7.	Alexan	60
8.	Alexan-100	60
9.	ALFENTA	52
10.	ALIMTA	54
11.	ALINIA	56
12.	Alisey	51

13.	Alkets	52
14.	ALLEGRA	52
15.	Allersol A	56
16.	AlleRx AM	51
17.	AlleRx PE AM	50
18.	ALOPRIM	52
19.	ALOXI	56
20.	Altekia	63
21.	Altex PSE	50
22.	Alupram	50
23.	Alustra	60
24.	Aluvea	52
25.	AREDIA	52
26.	Asepxia	65
27.	DEL-VI-A	53
28.	Diltia	53
29.	Gilenia	51
30.	Idaxia	55
31.	ILETIN I	54
32.	ILETIN II	52
33.	Ilex Skin	54
34.	KALETRA	50
35.	LENVIMA	52
36.	Lessina	57

37.	LESSINA-21	57
38.	LESSINA-28	57
39.	Levenia	52
40.	Levsin	52
41.	LEXIVA	61
42.	LYSTEDA	50
43.	Nalex-A	58
44.	Nalex-A 12	58
45.	NEULASTA	52
46.	OLYSIO	52
47.	ORENCIA	56
48.	Remsima	52
49.	Replesta	52
50.	Sleepia	56
51.	Sleeptien	50
52.	Solesta	55
53.	Sylevia	56
54.	Veltassa	54
55.	XYLO-PFAN	51
56.	Zylempha	54

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/s/

JUSTINE HARRIS
12/09/2014

IRENE Z CHAN
12/10/2014