CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

206185Orig1s000

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:	July 10, 2018
Application Type and Number:	NDA 206185
Product Name and Strength:	Xelpros (Latanoprost) Ophthalmic Emulsion, 0.005%
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Sun Pharma Global FZE
Panorama #:	2018-23225165
DMEPA Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xelpros, 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 re-submitted an external name study, previously conducted by [redacted] (b) (4), that DMEPA evaluated in our prior review.

1.1 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) found the name Xelpros*** conditionally acceptable under NDA 206185.[a]

Subsequently, on July 30, 2015, the Division of Transplant and Ophthalmology Products (DTOP) issued a Complete Response (CR) for the application. The Applicant re-submitted the application on July 28, 2016, and re-submitted the proposed proprietary name, Xelpros***, for our review. Again, we found the name, Xelpros***, conditionally acceptable on September 28, 2016.[b]

Subsequently, on December 19, 2016, DTOP issued a CR for the Application.

On November 30, 2017, a request was submitted to extend the time to resubmit the NDA to the CR letter on December 19, 2016.

Notification of the transfer of the NDA sponsorship from Sun Pharma Advanced Research Company, Ltd. to Sun Pharma Global FZE (SUN FZE) was received by the Agency on April 12, 2018.

Subsequently, the Applicant re-submitted the application on May 7, 2018, and re-submitted the proposed proprietary name, Xelpros***, for our review on May 22, 2018.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 22, 2018.

- Intended Pronunciation: Zel' prose
- Active Ingredient: latanoprost
- Indication of Use: reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
- Route of Administration: ophthalmic
- Dosage Form: sterile ophthalmic emulsion

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[a] Kapoor, R. Proprietary Name Review for Xelpros*** (NDA 206185). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 MAY 13. Panorama No. 2014-17043.

[b] Owens, L. Proprietary Name Review for Xelpros*** (NDA 206185). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2016 SEP 28. Panorama No. 2016-9946033.

- Strength: 0.005% (50 mcg/mL)
- Dose and Frequency: One drop in the affected eye(s) once daily in the evening.
- How Supplied: 2.5 mL emulsion filled in a 5 mL clear low density polyethylene bottle with a clear low density polyethylene dropper tip, and a turquoise high density polyethylene pilfer-proof cap.
    - Package of 1 bottle
    - Multi-pack of 3 bottles
- Storage: Protect from light. Store (b) (4) to 25°C (77°F). (b) (4)
  The bottle may be maintained at temperature up to 40°C (104°F) for a period not exceeding (b) (4) (b) (4)

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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Transplant and Ophthalmology Products (DTOP) 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[c].

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 6, 2018 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[c] USAN stem search conducted on May 23, 2018.

2.2.4 FDA Name Simulation Studies

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

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 99 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 review for the names evaluated previously. Therefore, we identified 30 names not previously analyzed. These names are included in Table 1 below.

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	30
Low similarity name pair: combined match percentage score ≤54%	0

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

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

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Transplant and Ophthalmology Products (DTOP) via e-mail on June 25, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DTOP on July 10, 2018, they stated no additional concerns with the proposed proprietary name, Xelpros.

3 CONCLUSION

The proposed proprietary name is acceptable.

[d] POCA search conducted on May 23, 2018 in version 4.2.

If you have any questions or need clarifications, please contact Danyal Chaudhry, OSE project manager, at 301-796-3813.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on May 22, 2018, 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 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.

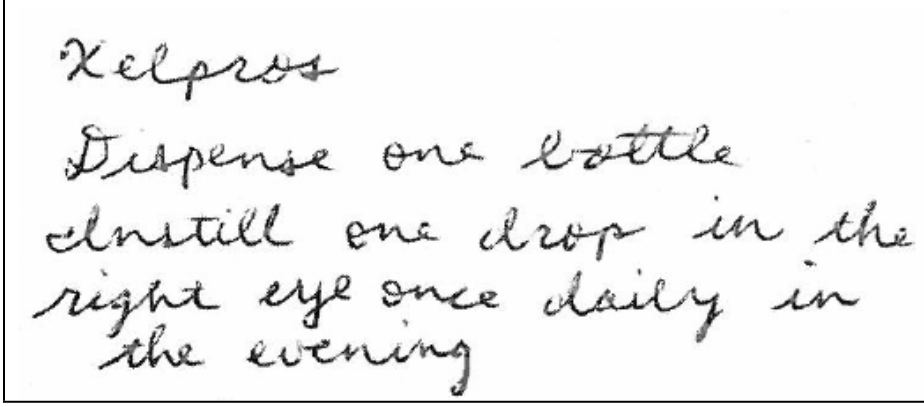
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Xelpros Study (Conducted on June 1, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Xelpros Dispense one bottle Instill one drop in right eye once daily in the evening.

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

307 People Received Study
53 People Responded

Study Name: Xelpros

Total	17	18	18	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
KELPROS	1	0	0	1
SELPROZE	0	1	0	1
XELPRO	0	0	6	6
XELPROS	16	0	12	28
ZELPROS	0	3	0	3
ZELPROSE	0	10	0	10
ZELPROZE	0	4	0	4

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

No.	**Proposed name:** **Established name:** **Dosage form:** **Strength(s):** **Usual Dose:**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	N/A		

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 (%)
1.	Alprolix	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:** **Established name:** **Dosage form:** **Strength(s):** **Usual Dose:**	**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.	Dextrose 50%	56	This name pair has sufficient orthographic and phonetic differences.
2.	Lexapro	54	This name pair has sufficient orthographic and phonetic differences.
3.	Lopressor	58	This name pair has sufficient orthographic and phonetic differences.
4.	Loprox TS	58	This name pair has sufficient orthographic and phonetic differences.
5.	Mepron	56	This name pair has sufficient orthographic and phonetic differences.
6.	(b) (4)***	52	This name pair has sufficient orthographic and phonetic differences.
7.	Prosol	54	This name pair has sufficient orthographic and phonetic differences.
8.	Tafluprost	55	This name pair has sufficient orthographic and phonetic differences.
9.	Xermelo	55	This name pair has sufficient orthographic and phonetic differences.
10.	Xtrelus***	58	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 (%)
1.	N/A	

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	Celiprolol	57	Active ingredient in an international product marketed in France, the United Kingdom, India, Poland, China, Netherlands, Belgium, Germany Chile, Greece, Hong Kong, Ireland, Switzerland, Japan, and the Czech Republic. Active ingredient in an international product formerly marketed in Greece, Spain, Russia, New Zealand, Italy, and Austria.
2.	Lopresor SR	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Oxaceprol	53	Active ingredient in an international product marketed in Germany, Argentina, and France. Active ingredient in an international product formerly marketed in Spain.
4.	Sloprolol	56	International product formerly marketed in the United Kingdom.
5.	Zipeprol	56	Active ingredient in an international product marketed in Greece. Active ingredient in an international product formerly marketed in Italy, Venezuela, Switzerland, France, Portugal, Spain, and Mexico.
6.	(b) (4)***	57	Proposed proprietary name for NDA 210806 found unacceptable by DMEPA (OSE# (b) (4)). Subsequently, the proposed proprietary name, Pifeltro*** was submitted for review under NDA 210806 and was found conditionally acceptable by DMEPA (2018-21573551). NDA 210806 is pending.

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 (%)
1.	Enpresse-21	55
2.	Enpresse-28	55
3.	Flo-Pred	59
4.	Folplex	56
5.	Pelodis	55
6.	Pifeltro***	56
7.	Poly Pred	56
8.	Poly-Pred	56
9.	(b) (4)***	63
10.	Selrx	62
11.	Serpex	56
12.	Sulparex	59
13.	Zulresso***	60

[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/

DEBORAH E MYERS
07/10/2018

OTTO L TOWNSEND
07/10/2018

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:	September 28, 2016
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Rx or OTC:	Rx
Applicant/Sponsor Name:	Sun Pharma Advanced Research Co LTD
Panorama #:	2016-9946033
DMEPA Primary Reviewer:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xelpros, 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 during this review cycle.

1.1 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) found the name Xelpros conditionally acceptable in OSE Review #2014-17043, dated May 13, 2014.

On July 30, 2015, the Division of Transplant and Ophthalmology Products (DTOP) issued a Complete Response (CR) for the application. The Applicant re-submitted the application on July 28, 2016, and re-submitted the proposed proprietary name, Xelpros, for our review.

1.2 PRODUCT INFORMATION

The following product information is provided in the July 28, 2016 proprietary name submission:

- Intended Pronunciation: Zel' prose
- Active Ingredient: Latanoprost
- Indication of Use: reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension
- Route of Administration: Ophthalmic
- Dosage Form: Ophthalmic Emulsion
- Strength: 0.005%
- Dose and Frequency: one drop in the affected eye(s) once daily in the evening
- How Supplied: 2.5 mL emulsion filled in a 5 mL clear low density polyethylene bottle with a clear low density polyethylene dropper tip, and a turquoise high density polyethylene pilfer-proof cap
- Storage: Protect from light. Store (b) (4) to 25°C (77°F). (b) (4)
  The bottle may be maintained at temperatures up to 40°C (104°F) for a period not exceeding (b) (4)

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 concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

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

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 12, 2016 email, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[b] organized as highly similar, moderately similar or low similarity for further evaluation. We identified 118 names in our POCA search. We had identified and evaluated 151 names in our previous proprietary name review.[c] 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 review for the names evaluated previously. **Table 1 includes 13 names not previously analyzed.**

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[a] USAN stem search conducted on September 1, 2016

[b] POCA search conducted on September 1, 2016.

[c] Kapoor, R Proprietary Name Review for Xelpros NDA . Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 May 13. RCM No.: 2014-17043.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	12
Low similarity name pair: combined match percentage score ≤49%	0

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

The proposed product, Xelpros will be available in strength of 0.005%. Since this is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with an overlap in strength and potential orthographic, spelling, and phonetic similarities with Xelpros that were not identified in POCA. We did not identify any names.

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

Our analysis of the 13 names contained in Table 1 determined that none of names will pose a risk for confusion as described in Appendices C through H.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Janet Higgins, OSE project manager, at 240-402-0330.

4 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your July 28, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

5 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

APPENDICES

Appendix A

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

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

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

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

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

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

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

   - Highly similar pair: combined match percentage score ≥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: • 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.

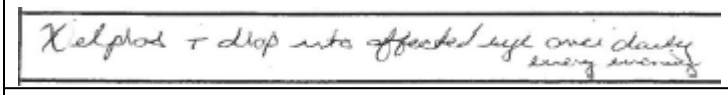
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 ≤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. Xelpros Study (Conducted on September 9, 2016)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Xelpros #1 UAD

Study Name: Xelpros
As of Date 9/21/2016

309 People Received Study
81 People Responded

Study Name: Xelpros

Total	28	21	32	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
XELPHAS	0	0	1	1
XELPHOS	0	0	9	9
XELPOR	1	0	0	1
XELPOS	0	0	1	1
XELPRAS	0	0	1	1
XELPRES	2	0	0	2
XELPROS	23	0	20	43
XELPROV	2	0	0	2
ZALPROSE	0	1	0	1
ZELPROS	0	11	0	11
ZELPROSE	0	8	0	8
ZELPROZ	0	1	0	1

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

No.	**Proposed name: Xelpros** **Established name: Latanoprost** **Dosage form: Ophthalmic Emulsion** **Strength(s): 0.005%** **Usual Dose: one drop in the affected eye(s) once daily in the evening**	**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.	Xelpros***	100	Name is the subject of this review

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.	Name	POCA Score (%)
1.	(b) (4)***	52
2.	Soluprep***	50
3.	Veltassa	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: Xelpros** **Established name: Latanoprost** **Dosage form: Ophthalmic Emulsion** **Strength(s): 0.005%** **Usual Dose: one drop in the affected eye(s) once daily in the evening**	**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.	Syndros	56	The prefixes/infixes of the name pair have sufficient orthographic differences. The first syllables of this name pair sound different
2.	(b) (4)***	56	The infixes/suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different
3.	Calphron	54	The prefixes/infixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different

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

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

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	58	Name found unacceptable in OSE RCM (b) (4) (b) (4). Applicant submitted the proposed proprietary name (b) (4)***, which is currently under review

No.	Name	POCA Score (%)	Failure preventions
2.	(b) (4)***	54	Secondary name for Soluprep***. The primary name was granted; however, the product received a complete response.
3.	(b) (4)***	53	Name found unacceptable in OSE RCM (b) (4) (b) (4). The product received a complete response and a new proposed proprietary name has not been submitted
4.	(b) (4)***	52	Name found unacceptable in OSE RCM (b) (4) (b) (4). A new proposed proprietary name has not been submitted
5.	Renaplus	50	Product is a veterinary drug product

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

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

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

No.	Name
1.	N/A

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

/s/

LISSA C OWENS
09/28/2016

MISHALE P MISTRY
09/28/2016

PROPRIETARY NAME MEMORANDUM

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:	July 13, 2015
Application Type and Number:	NDA 206185
Product Name and Strength:	Xelpros (Latanoprost) Ophthalmic (b) (4), 0.005%
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ora
Panorama #:	2015-384694
DMEPA Primary Reviewer:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

1 INTRODUCTION

The proposed proprietary name, Xelpros, was found conditionally acceptable in OSE Review # 2014-17043, under NDA 206185, dated May 13, 2014. We note that the product characteristics are the same. This memorandum is to communicate that DMEPA maintains the proposed proprietary name, Xelpros, is acceptable from both a misbranding and safety perspective.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager at 301-796-5413.

1.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 12, 2015 submission are altered, the name must be resubmitted for review.

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

/s/

SARAH K VEE
07/14/2015

YELENA L MASLOV
07/14/2015

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:	May 13, 2014
Application Type and Number:	NDA 206185
Product Name and Strength:	Xelpros (Latanoprost) Ophthalmic [redacted] (b) (4) 0.005%
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Ora
Submission Date:	March 5, 2014
Panorama #:	2014-17043
DMEPA Primary Reviewer:	Rachna Kapoor, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Xelpros, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study by the (b) (4) for this proposed proprietary name.

1.1 BACKGROUND

The proposed product is a 505 (b)(2) to Xalatan. It contains the same active ingredient and strength as Xalatan (NDA 020597, approved on June 5, 1996). However, Xalatan is made with a different preservative than Xelpros. Xelpros is formulated with castor oil and (b) (4) Therefore, Xelpros will have a different dosage form than Xalatan. Xalatan is manufactured by Pharmacia and Upjohn Company.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 5, 2014 proprietary name submission.

- Intended pronunciation: Zel' prose
- Active Ingredient: latanoprost
- Indication of Use: the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension
- Route of Administration: ophthalmic
- Dosage Form: ophthalmic (b) (4)
- Strength: 0.005%
- Dose and Frequency: instill one drop in the affected eye(s) once daily in the evening
- How Supplied: 5 mL (b) (4) low density polyethylene bottle (2.5 mL fill volume)
- Storage: (b) (4)

2 RESULTS

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

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Transplant and Ophthalmology Products (DTOP) concurred with the findings of OPDP's promotional 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 stated that there is no derivation or intended meaning for the proposed name, Xelpros, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

One hundred thirteen practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. In the written outpatient study, 38 of 39 participants correctly interpreted the prescription. In the written inpatient study, 35 of 40 participants correctly interpreted the prescription. Common misinterpretations in the written inpatient study were substitution of 'm' for 'r', and '5' for 's'. In the voice study, none of the 34 participants correctly interpreted the prescription. Common misinterpretations in the voice study include: 'z' for 'x', 'a' for 'e', 'c' for 'p', and 'v', 'x', and 'z' for 's'. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 19, 2014 e-mail, the Division of Transplant and Ophthalmology Products (DTOP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation.

[1]USAN stem search conducted on April 9, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	143
Low similarity name pair: combined match percentage score ≤49%	6

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

Our analysis of the one hundred fifty-one names contained in Table 1 determined one hundred fifty-one names will not pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Transplant and Ophthalmology Products (DTOP) via e-mail on May 5, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DTOP on May 6, 2014, they stated no additional concerns with the proposed proprietary name, Xelpros.

3 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Karen Townsend, OSE project manager, at 301-796-5413.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your March 5, 2014 submission are altered, 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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. 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. [2]

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

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 these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair do not share a common strength or dose (see Step 1 of the Moderately Similar Checklist).			
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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, 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 these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between moderately similar names **with** overlapping or similar strengths or doses.

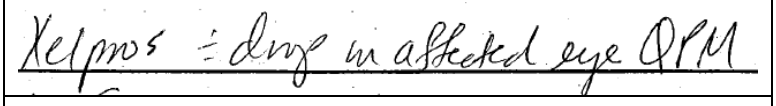
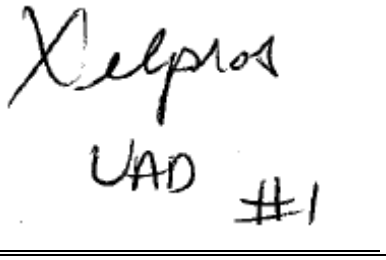
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Xelpros Study (Conducted on March 14, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  	Xelpros Use as Directed Disp. #1
Outpatient Prescription:  	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)
Study Name: Xelpros, As of Date 4/7/2014

274 People Received Study

113 People Responded

Total	**39**	**34**	**40**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
?	1	0	0	1
???	0	1	0	1
XELPMOS	0	0	1	1
XELPRO	0	0	1	1
XELPRO 5	0	0	1	1
XELPROS	38	0	35	73
XELPROS (EYE DROP)	0	0	1	1
XELPROSE	0	1	0	1
XELPROSS	0	0	1	1
ZALPROS	0	1	0	1
ZALPROSE	0	1	0	1
ZECROS	0	1	0	1
ZELCROOSE	0	1	0	1
ZELCROSE	0	2	0	2
ZELPRO	0	5	0	5
ZELPROS	0	11	0	11
ZELPROSE	0	4	0	4
ZELPROV	0	2	0	2
ZELPROX	0	1	0	1
ZELPROZ	0	3	0	3

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

No.	**Proposed name: Xelpros** **Strength: 0.005%** **Usual Dose: instill one drop in the affected eye(s) once daily in the evening**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion**
1.	none		

Appendix D: Moderately Similar Names (i.e., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Proposed Name	POCA Score (%)
1.	Diupres	62
2.	Diupres -250	62
3.	Diupres-500	62
4.	Zortress	59
5.	Xigris	58
6.	Delcort	58
7.	Iloprost	57
8.	Ferpront	56
9.	Vitaros	56
10.	Xiratuss	55
11.	Clorpres	54
12.	Milprem 200	54
13.	Milprem 400	54
14.	Relpax	54
15.	Xalkori	54
16.	Paltrase	54
17.	Detrol	53
18.	Zelnorm	53
19.	Giltuss	53
20.	Dextrose 25%	52

21.	Dextrose 60%	52
22.	Naprosyn	52
23.	Neupro	52
24.	Saphris	52
25.	Ultresa	52
26.	Unipres	52
27.	Valtrex	52
28.	Veletri	52
29.	Vesprin	52
30.	Zyloprim	52
31.	Key-Pred	52
32.	Teldrin	51
33.	Dacress	51
34.	Celebrex	50
35.	E-Z Prep	50
36.	E-Z Prep 220	50
37.	Velosef	50
38.	Velosef 125	50
39.	Velosef 250	50
40.	Velosef 500	50
41.	Zaleplon	50
42.	Zestril	50
43.	Caltro	50
44.	X-prep	50
45.	Ezambris	50

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

No.	**Proposed name: Xelpros** **Strength: 0.005%** **Usual Dose: instill one drop in the affected eye(s) once daily in the evening**	**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.	Zaltrap	62	The infix and suffix of this name pair have sufficient orthographic differences. The last syllable in both names gives the names a distinctly different sound when spoken.
2.	Zelboraf	60	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Zelboraf and the last syllable in both names give the names a distinctly different sound when spoken.
3.	Velphoro	59	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Velphoro and the last syllable in both names give the names a distinctly different sound when spoken.
4.	Elaprase	57	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
5.	Colcrys	56	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Colcrys and the last syllable in both names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
6.	Eliphos	54	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Eliphos and the first syllable in both names give the names a distinctly different sound when spoken.
7.	Soliris	54	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Soliris and the last syllable in both names give the names a distinctly different sound when spoken.
8.	Daypro	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
9.	Folvron	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
10.	Reopro	52	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
11.	Rezipas	52	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Rezipas and the first syllable in both names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
12.	Xibrom	52	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
13.	Zelapar	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Zelapar and the last syllable in both names give the names a distinctly different sound when spoken.
14.	Xerese	51	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
15.	Ferriprox	50	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Ferriprox and the first syllable in both names give the names a distinctly different sound when spoken.
16.	Kyprolis	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
17.	Ser-ap-es	50	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
18.	Sulphrin	50	The suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Sulphrin and the last syllable in both names give the names a distinctly different sound when spoken.
19.	Xylose	50	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
20.	Debrox	58	The prefix and infix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
21.	Marpres	58	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable in both names gives the names a distinctly different sound when spoken.
22.	Selenos	58	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Selenos and the last syllable in both names give the names a distinctly different sound when spoken.
23.	Deproist	56	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
24.	X-Seb Plus, X-Seb T Plus	56, 50	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in these names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
25.	Valproate	55	The suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
26.	Calphron	54	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
27.	Nephrox	54	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
28.	Seb-Prev	54	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
29.	Nalfrx	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
30.	Peleverus	52	The prefix and infix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
31.	Zephrex	52	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
32.	Bel-Tabs	51	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
33.	Certuss	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
34.	Dispas	50	The prefix and infix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
35.	DSS Plus	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
36.	Entre-S	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
37.	Ferraplus	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
38.	Respirol	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
39.	Wal-Profen	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
40.	Zorprin	50	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
41.	Loprox	53	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable in both names gives the names a distinctly different sound when spoken.
42.	Relcof, Relcof C	54, 50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
43.	Milprosa	66	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The last syllable in Milprosa and the first syllable in both names give the names a distinctly different sound when spoken.
44.	Colprep	56	The prefix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
45.	Sympres	56	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable in both names gives the names a distinctly different sound when spoken.

No.	Proposed name: Xelpros Strength: 0.005% Usual Dose: instill one drop in the affected eye(s) once daily in the evening	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
46.	Xultophy	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second syllable in Xultophy and the last syllable in both names give the names a distinctly different sound when spoken.

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

No.	Name	POCA Score (%)
1.	Salonpas	≤49%
2.	Xalatan	≤49%
3.	Xeloda	≤49%
4.	Xenazine	≤49%
5.	Xenical	≤49%
6.	Xolair	≤49%

Appendix G: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)	82	Name entered by safety evaluator in POCA database. The name was not reviewed. Original sponsor that sent in the trade name (Sonus Pharmaceuticals) has been bought out by Eagle Pharmaceuticals. This IND (b) (4) has been deactivated.
2.	(b) (4)	70	In OSE RCM# (b) (4) the name was denied (b) (4). The proprietary name approved under this NDA 022173 was Zyprexa Relprevv on December 11, 2009.
3.	Gelprox	66	Name entered by safety evaluator in POCA database. Unable to find product characteristics in commonly used drug databases.
4.	(b) (4)	66	The name was denied in OSE RCM (b) (4) on July 8, 2010. This (b) (4) is in complete response status since July 20, 2010.
5.		61	This is a secondary proposed proprietary name and the product was approved under proprietary name Juxtapid on December 21, 2012 under NDA 203858.
6.		60	This is a secondary proposed proprietary name and the product was approved under proprietary name Atralin on July 26, 2007 under NDA 022070.
7.		60	This is a secondary proposed proprietary name and the product was approved under name levonorgestrel and ethinyl estradiol on October 23, 2012 under ANDA 091440.
8.		60	This NDA 022202 was approved with the proprietary name Zipsor on June 16, 2009.
9.		60	This name was withdrawn by the Applicant in OSE RCM (b) (4) as of April 22, 2013.
10.		58	This is a secondary proposed proprietary name and the product is currently being reviewed under the proprietary name Mitigare under NDA 204820.
11.		58	This is a secondary proposed proprietary name. This (b) (4) is in complete response status since December 27, 2013.

No.	Name	POCA Score (%)	Failure preventions
12.	Metoros	57	International product marketed in Austria.
13.	Cypress	57	Name entered by safety evaluator in POCA database. Product is not a drug. It refers to Cypress Pharmaceutical, Inc.
14.	(b) (4)	57	In OSE RCM (b) (4) the name was denied (b) (4) (b) (4) (b) (4). The proprietary name approved under this NDA 202278 was Zecuity on January 17, 2013.
15.	Solprin	56	International product marketed in Australia and New Zealand.
16.	Mallopress	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	(b) (4)	56	This is a tertiary proposed proprietary name and the product was approved under the secondary proprietary name Caprelsa on April 6, 2011 under NDA 022405.
18.	Kelferon	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	(b) (4)	54	In OSE RCM (b) (4) the name was denied (b) (4) (b) (4) (b) (4). Another proprietary name has not been submitted at this time.
20.	Valrox	53	International product marketed in United Kingdom.
21.	Ultrase	53	International product marketed in Canada.
22.	(b) (4)	53	In OSE RCM (b) (4) the name was denied (b) (4) (b) (4). The proprietary name approved under this NDA 022222 was Ultresa on March 1, 2012.
23.	Dinoprost	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	Dipro	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
25.	Fepron	52	International product marketed in Italy, Netherlands, and Germany.
26.	Ralgro	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Zavedos	52	International product marketed in many other countries including United Kingdom, Thailand, Sweden, Spain, and Italy.
28.	(b) (4)	52	In OSE RCM (b) (4) the name was found unacceptable by DDMAC (b) (4) (b) (4). The name was not reviewed by DMEPA. This (b) (4) is inactive status since December 8, 2011.
29.	(b) (4)	52	This is a secondary proposed proprietary name and the product was approved under proprietary name Fulyzaq on December 31, 2012 under NDA 202292.
30.	Valtrum	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Xylarex	51	Product is not a drug. It is medical food.
32.	(b) (4)	51	On December 11, 2013, FDA received the official submission of the cover letter from the Applicant, dated November 22nd, that they are withdrawing the proprietary name request dated August 3, 2010 which proposed (b) (4). The Applicant will resubmit the request for Proprietary Name Review when they will be submitting the response to the Complete Response Letter dated April 16, 2013.
33.	Neuprex	51	Name entered by safety evaluator in POCA database. Unable to find product characteristics in commonly used drug databases.
34.	Reziris	51	Name entered by safety evaluator in POCA database. Unable to find product characteristics in commonly used drug databases.
35.	Felypressin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
36.	Gemeprost	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Voltarol	50	International product marketed in Ireland, United Kingdom, and Norway.
38.	Xebcort	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Zentrip	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Zuprevo	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Xylitol	50	Product is not a drug. It is a sweetener.
42.	(b) (4)	50	In OSE RCM (b) (4) the name was denied (b) (4) (b) (4) (b) (4). The name approved under this ANDA 091234 was desogestrel and ethinyl estradiol on July 12, 2013.
43.	(b) (4)	50	This name was withdrawn by the Applicant in OSE RCM# (b) (4) as of February 18, 2011.
44.	(b) (4)	50	Tradename review was not performed due to the Applicant submitting a new supplement requesting approval without a tradename. Approval letter from OGD sent 7/15/2008. The name approved under this ANDA 078182 was divalproex sodium on July 29, 2008.
45.	(b) (4)	50	This is a secondary proposed proprietary name and the product was approved under proprietary name Olysio on November 22, 2013 under NDA 205123.
46.	Letaris	50	Name entered by safety evaluator in POCA database. Unable to find product characteristics in commonly used drug databases.
47.	(b) (4)	50	This is a tertiary proposed proprietary name and the product was approved under proprietary name Stendra on April 27, 2012 under NDA 202276.

No.	Name	POCA Score (%)	Failure preventions
48.	(b) (4)	50	In OSE RCM (b) (4) the name was denied (b) (4) (b) (4) (b) (4). Another proprietary name has not been submitted at this time.
49.	(b) (4)	50	In OSE RCM (b) (4) the name was found unacceptable by DDMAC from a promotional perspective. The name was not reviewed by DMEPA. The proprietary name approved under this NDA 022180 was Feraheme on June 30, 2009.
50.	Xebrazol	50	Name entered by safety evaluator in POCA database. Unable to find product characteristics in commonly used drug databases.
51.	(b) (4)	50	This is a secondary proposed proprietary name and the product was approved under proprietary name Gilotrif on July 12, 2013 under NDA 201292.
52.	(b) (4)	50	In OSE (b) (4) the name was found unacceptable by DDMAC from a promotional perspective. The name was not reviewed by DMEPA. The proprietary name approved under this NDA 021997 was Edluar on March 13, 2009.

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/s/

RACHNA KAPOOR
05/13/2014

YELENA L MASLOV
05/14/2014