

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

214375Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 27, 2022
Application Type and Number:	NDA 214375
Product Name and Strength:	Xenoview (hyperpolarized xenon Xe 129) Gas, 1,000 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Polarean, Inc. (Polarean)
PNR ID #:	2022-1044724590
DMEPA 2 Safety Evaluator:	Devin Kane, PharmD
DMEPA 2 Team Leader:	Hina Mehta, PharmD
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Xenoview, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A, respectively. Polarean did not submit an external name study for this proposed proprietary name. Polarean submitted their results from an internally conducted name study for this proposed proprietary name that was previously reviewed.^a

1.1 REGULATORY HISTORY

Polarean previously submitted the proposed proprietary name, Xenoview*** on October 2, 2020 under NDA 214375. The proposed proprietary name was found conditionally acceptable on December 29, 2020.^b However, this application received a complete response (CR) letter on October 5, 2021.^c

Polarean submitted the name, Xenoview, for review on May 16, 2022 as part of the resubmission for NDA 214375.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on May 16, 2022.

- Intended Pronunciation: zeen-oh-view
- Active Ingredient: hyperpolarized xenon Xe 129
- Indication of Use: (b) (4)
- Route of Administration: For Inhalation
- Dosage Form: Gas
- Strength: 1,000 mL
- Dose and Frequency: The recommended dose of Xenoview is 75 mL DE (Dose Equivalent)^d of hyperpolarized Xe-129 gas with a range of 250 mL to 750 mL total Xe.

^a Polarean Inc. included all POCA results retrieved from POCA with a score of greater or equal to 50. For the purpose of this review, we only included names identified from the external POCA search with moderate or high similarity.

^b Kane, D. Proprietary Name Review for Xenoview (NDA 214375). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 28. PNR ID No. 2020-43291889.

^c Skarupa, L. Complete Response Letter. 2021 OCT 05. Available from: <https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8061b430>

^d According to the proposed Prescribing Information, DE (Dose Equivalent) is derived by the following formula:

(b) (4)

- How Supplied: (b) (4) gas blend for preparation of Xenoview is supplied in aluminum cylinders as a compressed gas under high pressure (2,105 pounds per square inch gauge [psig]) in size 302 aluminum cylinders; a volume of 6,350 liters.
 - Storage: Store Xenoview gas blend at (b) (4) 20° to 25°C (68° to 77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F).
-

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Xenoview would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Xenoview. The Division of Medical Imaging and Radiation Medicine (DMIRM) did not comment on the findings of OPDP's assessment for Xenoview.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proposed proprietary name^e.

2.2.2 *Components of the Proposed Proprietary Name*

Polarean indicated in their submission that the proposed proprietary name, Xenoview, is derived from the active ingredient xenon and viewing an image. 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 can contribute to medication error.

^e USAN stem search conducted on May 27, 2022.

2.2.3 Comments from Other Review Disciplines at Initial Review

On June 15, 2022, the Division of Medical Imaging and Radiation Medicine (DMIRM) did not forward any comments or concerns relating to Xenoview at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred and nine (109) practitioners participated in DMEPA's prescription studies for Xenoview. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search^f identified 69 names with the combined score of $\geq 55\%$ or individual orthographic or phonetic score of $\geq 70\%$. We had identified and evaluated some of the names in our previous proprietary name review. 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 2 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	0
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	2
Low similarity name pair: combined match percentage score $\leq 54\%$	0

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

Our analysis of the 2 names contained in Table 1 determined none of the names will pose a risk for confusion with Xenoview as described in Appendices C through H.

^f POCA search conducted on May 27, 2022 in version 4.4.

2.2.8 *Communication of DMEPA's Determination*

On July 27, 2022, DMEPA 2 communicated our determination to the Division of Medical Imaging and Radiation Medicine (DMIRM).

3 CONCLUSION

The proposed proprietary name, Xenoview, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO POLAREAN, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 16, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

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. ^g

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

***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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names^h. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may 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 <u>with</u> 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Xenoview Study (Conducted on June 3, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> <i>Xenoview Inhale 75mL dose equivalent of hyperpolarized Xe 129</i>	Xenoview Bring to Clinic #1
<u>Outpatient Prescription:</u> Patient _____ Date _____ Address _____ R <i>Xenoview</i> <i>Bring to Clinic</i> <i>#1</i>  MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. <u>OSE</u> _____ DEA No. _____ Address _____ Telephone _____	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font) Xenoview	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
109 People Responded

Study Name: Xenoview

Total	23	26	26	34	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
XENOVERN	0	0	0	1	1
XENOVUE	23	26	7	29	85
XENOVUE INHALE	0	0	0	4	4
XENOVUE	0	0	2	0	2
ZENO VUE	0	0	1	0	1
ZENOVUE	0	0	4	0	4
ZENOVUE	0	0	10	0	10
ZINOVUE	0	0	1	0	1
ZINOVUE	0	0	1	0	1

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

Appendix D: Moderately Similar Names (e.g., combined POCA score is $\geq 55\%$ to $\leq 69\%$) with no overlap or numerical similarity in Strength and/or Dose – N/A

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

No.	Proposed name: Xenoview Established name: hyperpolarized xenon Xe 129 Dosage form: Gas Strength(s): 1,000 mL Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
2.	Aponvie***	55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$) – N/A

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

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusionⁱ. – N/A

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

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PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 28, 2020
Application Type and Number:	NDA 214375
Product Name and Strength:	Xenoview (hyperpolarized Xe 129) gas, 1 L
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Polarean, Inc. (Polarean)
Panorama #:	2020-43291889
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Xenoview, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Polarean submitted their results from an internally conducted name study for this proposed proprietary name.^a

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 2, 2020.

- Intended Pronunciation: zeen-oh-view
- Active Ingredient: hyperpolarized Xe 129
- Indication of Use: (b) (4)
- Route of Administration: for inhalation
- Dosage Form: gas
- Strength: 1 L
- Dose and Frequency: The recommended dose of Xenoview is 75 mL DE (Dose Equivalent)^b of hyperpolarized Xe-129 gas with a range of 250 mL to 750 mL total Xe
- How Supplied: (b) (4) gas blend for preparation of Xenoview is supplied in aluminum cylinders as a compressed gas under high pressure (2,105 pounds per square inch gauge [psig]) in size 302 aluminum cylinders; a volume of 6,350 liters.
- Storage: Store Xenoview gas blend at (b) (4) 20° to 25°C (68° to 77°F), with excursions permitted to 15°C to 30°C (59°F to 86°F).

(b) (4)

^a Polarean Inc. included all POCA results retrieved from POCA with a score of greater or equal to 50. For the purpose of this review, we only included names identified from the external POCA search with moderate or high similarity.

^b According to the proposed Prescribing Information, DE (Dose Equivalent) is derived by the following formula:

(b) (4)

(b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Xenoview would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Medical Imaging and Radiation Medicine (DMIRM) concurred with the findings of OPDP's assessment for Xenoview.

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

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

2.2.2 *Components of the Proposed Proprietary Name*

Polarean indicated in their submission that the proposed proprietary name, Xenoview, is derived from the active ingredient xenon and viewing an image. 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, October 30, 2020 e-mail, the Division of Medical Imaging and Radiation Medicine (DMIRM) did not forward any comments or concerns relating to Xenoview at the initial phase of the review.

2.2.4 *FDA Name Simulation Studies*

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

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Our POCA search^d identified 67 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

^c USAN stem search conducted on November 19, 2020.

^d POCA search conducted on October 27, 2020 in version 4.4.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the internal study conducted by Polarean.^e These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	65
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 67 names contained in Table 1 determined none of the names will pose a risk for confusion with Xenoview as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Medical Imaging and Radiation Medicine (DMIRM) via e-mail on December 21, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Medical Imaging and Radiation Medicine (DMIRM) on December 28, 2020, they stated no additional concerns with the proposed proprietary name, Xenoview.

3 CONCLUSION

The proposed proprietary name, Xenoview, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui-Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO POLAREAN, INC.

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

^e Polarean Inc. included all POCA results retrieved from POCA with a score of greater or equal to 50. For the purpose of this review, we only included names identified from the external POCA search with moderate or high similarity

If any of the proposed product characteristics as stated in your submission, received on October 2, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

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.^f

^f National Coordinating Council for Medication Error Reporting and Prevention. <https://www.nccmerp.org/about-medication-errors> Last accessed 10/05/2020.

***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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

- Low similarity: combined match percentage score $\leq 54\%$.

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 names⁸. 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

⁸ Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is $\geq 55\%$ to $\leq 69\%$).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may 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 <u>with</u> overlapping or similar strengths or doses.

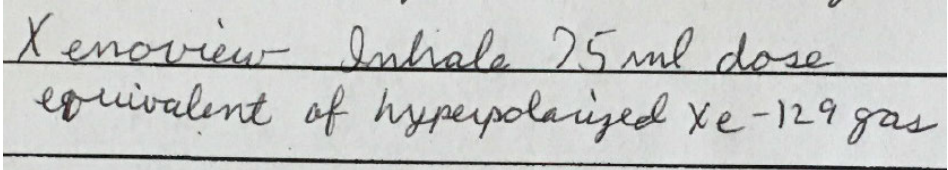
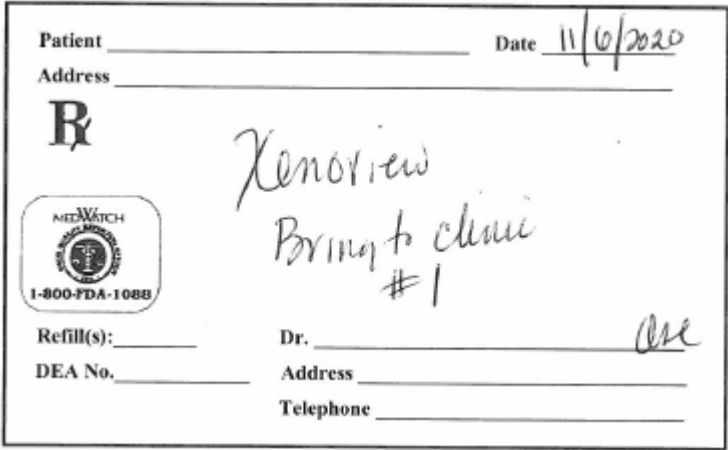
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

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. Xenoview Study (Conducted on November 6, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Xenoview Bring to Clinic #1
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Xenoview	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study
85 People Responded

Study Name: Xenoview

Total	17	23	18	27	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
VENAVUE	0	0	1	0	1
VENOVUE	0	0	0	1	1
XENAVUE	0	0	1	0	1
XENAVUE	0	0	1	0	1
XENORVIEW	1	0	0	0	1
XENOVUE	16	23	1	23	63
XENOVUE INHALE	0	0	0	2	2
XENOVUE INHALER	0	0	0	1	1
ZEENAVUE	0	0	1	0	1
ZENAVUE	0	0	4	0	4
ZENAVUE	0	0	6	0	6
ZENOVUE	0	0	1	0	1
ZINAVEUX	0	0	1	0	1
ZINAVUE	0	0	1	0	1

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

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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.	Xenoview***	100	Name being evaluated by study.

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

No.	Name	POCA Score (%)
1.	Januvia	57

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

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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.	Xenazine	66	Orthographically, when written with the downstroke letter ‘z’ in the fifth position in Xenazine, the downstroke letter ‘z’ that is absent from Xenoview provides sufficient orthographic differences. When written without the downstroke ‘z’ in Xenazine, the suffix (view vs. zine) still provides some orthographic differences. Phonetically, the third syllables (‘zine’ vs. ‘view’) provides sufficient phonetic differences.

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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
			Although both Xenoview and Xenazine can have numerical similarity dose (75 mL dose equivalent vs. 75 mg), this name pair differs in strength (1L vs. 12.5 mg and 25 mg), dosage form (gas vs. tablet), route of administration (inhalation vs. oral), and frequency of administration (once vs. once daily to three times daily). Thus, these product characteristic differences provide additional differentiation if included on a prescription. Additionally, Xenoview is supplied as a large cylinder tank that will be delivered directly from the manufacturer to the facility such as the imaging suite, where the medication use process from ordering (separate ordering/CPOE system from drugs in central pharmacy) to administration (order by radiologist and administered under the ordering radiologist's supervision) do not overlap with the medication use process of Xenazine. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Venofer	64	This name pair has sufficient orthographic and phonetic differences.
3.	Myoview	63	This name pair has sufficient orthographic and phonetic differences.
4.	Xenon Xe 133	63	Orthographically, the root name Xenon is comprised of 5 letters, whereas Xenoview is comprised of 8 letters. The suffix (-on vs -view) look different when scripted. Additionally, we note

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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
			the presence of modifiers ‘Xe 133’, which is not seen in Xenoview and provides additional orthographic differences from Xenoview when included on a prescription. Phonetically, Xenon is comprised of 2 syllables, whereas Xenoview is comprised of three syllables. The last syllable (-on vs -view) of the name pair sound different. Additionally, we note the presence of modifiers ‘Xe 133’, which provides additional phonetic differences from Xenoview when included on in the verbal order. Although both Xenon Xe 133 and Xenoview have the same dosage form (gas) and route of administration (inhalation), this name pair differs in strength (1 L vs. 10 mCi or 20 mCi), and dose (75 mL dose equivalent vs. 2 mCi to 30 mCi (74 MBq to 1110 MBq)). We note Xenon Xe 133 and Xenoview would appear in the same CPOE ordering system, where Xenon Xe 133 is currently the only drug product under the letter string “xen” or “xeno”, which raises concern for CPOE name confusion errors. If a radiologist inadvertently selects the radioactive Xenon Xe 133 instead of the intended Xenoview in the CPOE system, s/he will be prompted to enter the calibration date/time, which would flag

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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
			the ordering radiologist because Xenoview is not radioactive and would not have a calibration date/time. If a nuclear medicine physician inadvertently selects the nonradioactive Xenoview in the CPOE system, the lack of place to enter the calibration date/time will flag the ordering nuclear medicine physician who routinely enters this information for radiopharmaceuticals they order in their typical clinical practice. When considering the above, the risk of CPOE error is minimized.
5.	Cysview	60	This name pair has sufficient orthographic and phonetic differences.
6.	Xenpozyme***	60	This name pair has sufficient orthographic and phonetic differences.
7.	Adreview	59	This name pair has sufficient orthographic and phonetic differences.
8.	Renova	59	This name pair has sufficient orthographic and phonetic differences.
9.	Tenofovir	59	This name pair has sufficient orthographic and phonetic differences.
10.	Xenon-133	58	The FDA approved drug labeling uses the proprietary name Xenon Xe 133 per Drugs@FDA, however, we recognize some CPOE systems may include and prescribers may write “Xenon-133” instead, thus, we include Xenon-133 in our evaluation. Orthographically, Xenon is comprised of 5 letters, whereas Xenoview is comprised of 8 letters. The suffix (-on vs -view) look different when scripted.

No.	Proposed name: Xenoview Established name: hyperpolarized Xe 129 Dosage form: gas Strength(s): 1 L Usual Dose: Inhale 75 mL dose equivalent of hyperpolarized Xe-129 gas with a range of 250 mL and 750 mL total Xe	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
			Phonetically, Xenon is comprised of 2 syllables, whereas Xenoview is comprised of three syllables. The last syllable (-on vs -view) of the name pair sound different. Also see “Xenon Xe 133” above.
11.	Chenodiol	57	This name pair has sufficient orthographic and phonetic differences.
12.	Xpovio	57	This name pair has sufficient orthographic and phonetic differences.
13.	Adenosine	56	This name pair has sufficient orthographic and phonetic differences.
14.	Xenical	55	This name pair has sufficient orthographic and phonetic differences.

Appendix F: Low Similarity Names (e.g., combined POCA score is $\leq 54\%$) – 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) ***	69	Proposed proprietary name for IND 073916 denied on April 22, 2019. Sponsor submitted the proposed proprietary name, Rukobia*** (OSE # 2019-35884560), for review and it was found conditionally acceptable on November 1, 2019.
2.	Renovue-65	68	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
3.	Fenoverine	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
4.	Enovid-E	65	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 010976 withdrawn FR effective 06/18/2009.
5.	Enovid-E 21	65	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 010976 withdrawn FR effective 06/18/2009.
6.	Venomil	63	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
7.	Xenon Xe 127	63	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 018536 withdrawn FR effective 06/18/2009.
8.	Tanovea	62	Product is a veterinary drug product.
9.	Zimovane	62	International drug product marketed in Ireland and United Kingdom.
10.	Enovid	61	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 010976 withdrawn FR effective 06/18/2009.
11.	Renovist	60	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
12.	Synovex	60	Product is a veterinary drug product.
13.	Innovace	58	International drug product marketed in Ireland and United Kingdom.
14.	Renovist Ii	58	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
15.	Technivie	58	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
16.	Xeneisol	58	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 017262 withdrawn FR effective 06/25/1993.
17.	Xenaderm	58	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.

No.	Name	POCA Score (%)	Failure preventions
18.	Xenon	58	We note that Xenon alone is an element, not a drug, and specific isotopes of Xenon can be used in the field of medical imaging. Xenoview is comprised of the isotope Xenon Xe 129. We note that the radioactive isotope Xenon Xe 133 is indicated for evaluation of pulmonary function and for imaging of the lungs. We assess the name pair of Xenoview and Xenon Xe 133 above.
19.	Betnovate	56	International drug product formerly marketed in Chile and Czech Republic.
20.	Genozol	56	International product formerly marketed in Italy.
21.	Inoven	56	International drug product formerly marketed in the United Kingdom.
22.	Phenobel	56	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
23.	Renovue-Dip	56	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
24.	Xenon Xe 133 V.S.S.	56	Brand discontinued per Drugs@FDA with no generic equivalents available. NDA 017687 withdrawn FR effective 04/04/2005.
25.	(b) (4) ***	56	Proposed proprietary name for INDs 106594 and 125546 found unacceptable by DMEPA (OSE# 2018-24380138 and 24406170). NDAs 211672 and 211673 approved under the proprietary name Xenleta on June 20, 2019.
26.	Ergonovine	55	Name identified in RxNorm database. Per Redbook, product is deactivated with no generic equivalents available.
27.	Enoximone	52	International product marketed in Germany, UK, Italy, Netherlands and France.

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

No.	Name	POCA Score (%)
1.	Denavir	61
2.	Fensolvi	60
3.	Rena-Vite	60
4.	Sennoside B	60
5.	Denaverine	58
6.	Menveo	58
7.	Vanoxide	58
8.	Ventavis	57
9.	Fennel Oil	56
10.	(b) (4) ***	56
11.	Ketovail	56
12.	Lemon Oil	56
13.	Nuvileo	56
14.	Temovate	56
15.	Temovate E	56
16.	Vendone	56
17.	Ventaire	56
18.	Zenavod	56
19.	Zidovudine	56
20.	Zinotic Es	56
21.	Genvoya	55
22.	Kentovace	55
23.	Lenvima	55
24.	Vonvendi	55

^h 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

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/s/

DEVIN R KANE
12/28/2020 02:13:19 PM

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12/28/2020 04:38:54 PM