CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215973Orig1s000
215974Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	August 10, 2022
Application Type and Number:	NDA 215973 NDA 215974
Product Name and Strength:	Sunlenca (lenacapavir) Injection: 463.5 mg/1.5 mL (309 mg/mL) Tablet: 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Sciences, Inc. (Gilead)
PNR ID #:	2022-1044724643 (NDA 215973) 2022-1044724644 (NDA 215974)
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph.
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Sunlenca, 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. Gilead submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external name study was previously reviewed under IND 136260 (see Section 1.1 below).

1.1 REGULATORY HISTORY

The proposed proprietary name, Sunlenca***, was found unacceptable under NDA 215973 and NDA 215974 on April 8, 2022.[a] The proposed proprietary name, Sunlenca***, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) *** (b) (4), under review at the time (BLA 761263). Therefore, the ultimate acceptability of the proposed proprietary name, Sunlenca***, was dependent upon which underlying application was approved first.

Gilead responded to a Complete Response (CR) and re-submitted the name, Sunlenca, for review under NDA 215973 and 215974 on June 27, 2022.

(b) (4) ***.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 27, 2022.

- Intended Pronunciation: sun-LEN-kuh
- Active Ingredient: lenacapavir
- Indication of Use: Treatment of HIV-1 infection
- Route of Administration: subcutaneous, oral
- Dosage Form: Injection; Tablet
- Strength: Injection: 463.5 mg/1.5 mL (309 mg/mL); Tablet: 300 mg
- Dose and Frequency:

  Recommended dosage – Initiation with one of two options followed by once every 6-months maintenance dosing.

  Initiation Option 1

[a] Mena-Grillasca, C. Proprietary Name Review for Sunlenca*** (NDA 215973 & NDA 215974). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Apr 08. PNR ID No. 2021-1044724041-1 & 2021-1044724042-1.

Day 1 927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 tablets)

Day 2 600 mg orally (2 tablets)

Initiation Option 2

Day 1 600 mg orally (2 tablets)

Day 2 600 mg orally (2 tablets)

Day 8 300 mg orally (1 tablet)

Day 15 927 mg by subcutaneous injection (2 x 1.5 mL injections)

Maintenance

927 mg by subcutaneous injection (2 x 1.5 mL injections) every 6 months (26 weeks) from the date of the last injection +/-2 weeks.

- How Supplied:

  Injection: packaged in a dosing kit containing:

  -2 single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of lenacapavir. Vials are sealed with a stopper and aluminium overseal with flip-off cap.

  -2 vial access devices, 2 disposable syringes, and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).

  Tablets: packaged in a blister pack containing 4 tablets or 5 tablets. Each tablet contains 300 mg of lenacapavir.

- Storage: Both formulations (i.e. oral loading dose and subcutaneous injection) of this product should be stored at 25 °C (77 °F), excursions permitted to 15–30 °C (59–86 °F).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Sunlenca would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Sunlenca. The Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Sunlenca.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Gilead indicated in their submission that the proposed proprietary name, Sunlenca, is derived from a combination of letters which is devoid of meaning. 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

On August 8, 2022, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Sunlenca at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (n=90) practitioners participated in DMEPA's prescription studies for Sunlenca. 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[c] 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 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 also note that the product storage has changed from '(b) (4)' to '25 °C (77 °F), excursions permitted to 15–30 °C (59–86 °F)'. No other product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified five 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. 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 ≥70%	1

[b] USAN stem search conducted on July 7, 2022.

[c] POCA search conducted on July 7, 2022 in version 4.4.

Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
Low similarity name pair: combined match percentage score ≤54%	2

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

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

2.2.8 Communication of DMEPA's Determination

On August 10, 2022, DMEPA 1 communicated our determination to the Division of Antivirals (DAV).

3 CONCLUSION

The proposed proprietary name, Sunlenca, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor-Lebbie, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO GILEAD SCIENCES, INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 27, 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. [d]

[d] 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 ≥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[e]. 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

[e] 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 ≥ 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.

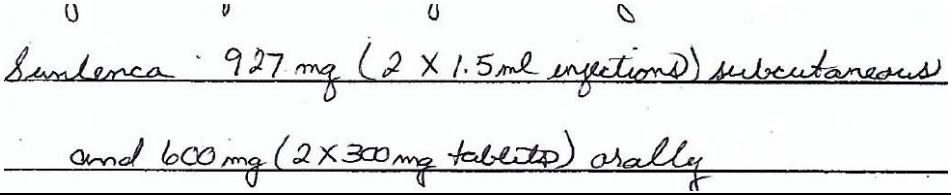
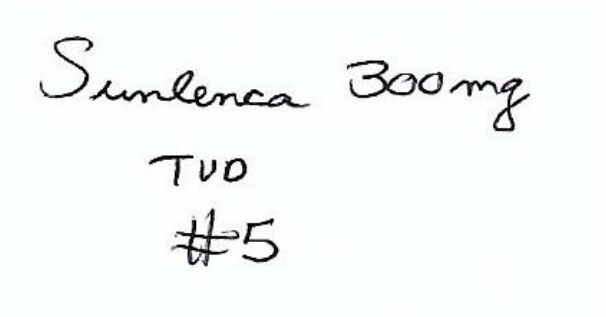
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Sunlenca Study (Conducted on July 22, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Sunlenca 300 mg TUD #5
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Sunlenca	

Study Name: Sunlenca
As of Date 8/4/2022

262 People Received Study
90 People Responded

Study Name: Sunlenca

Total	27	22	15	26	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
SANLENCA	1	0	0	0	1
SEMLANCA	0	0	1	0	1
SEMLENCA	0	0	0	1	1
SENLENCA	0	0	0	1	1
SIMBENCA	0	0	0	1	1
SIMLENCA	0	0	0	3	3
SINLENCA	0	0	0	1	1
SUBLINKA	0	0	1	0	1
SUMLENCA	2	0	0	2	4
SUNBENCA	1	0	0	0	1
SUNLANCA	0	0	1	0	1
SUNLANKA	0	0	10	0	10
SUNLENCA	22	22	0	16	60
SUNLENCA 300 MG	0	0	0	1	1
SUNLYNCA	0	0	1	0	1
SUNLYNKA	0	0	1	0	1
SYNLENCA	1	0	0	0	1

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

No.	**Proposed name:** Sunlenca **Established name:** lenacapavir **Dosage form:** Injection; Tablet **Strength(s):** Injection: 463.5 mg/1.5 mL (309 mg/mL); Tablet: 300 mg **Usual Dose:** Day 1-927 mg by subcutaneous injection (2 x 1.5 mL injections) and 600 mg orally (2 tablets) Day 2-600 mg orally (2 tablets)	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.	Sunlenca***	100	Name subject of this review

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

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

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

No.	Name	POCA Score (%)
1.	Kisunla	54
2.	Seconal	50

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.	Solensia	67	Veterinary product
2.	(b) (4) ***	62	Proposed proprietary name for (b) (4) previously found to be unacceptable due to orthographic and phonetic similarities to the pending proprietary name, Sunlenca, which is the subject of this review. Per submission dated August 2, 2022, the Applicant has stated that the proposed proprietary name for (b) (4) ***.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[f]-N/A

[f] 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

APPEARS THIS WAY ON ORIGINAL

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/

MELINA N FANARI
08/10/2022 03:28:38 PM

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MISHALE P MISTRY
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PROPRIETARY NAME MEMORANDUM

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

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Applicant/Sponsor Name:	Gilead Sciences, Inc. (Gilead)
PNR ID #:	2021-1044724041-1 2021-1044724042-1
DMAMES Safety Evaluator:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Associate Director of Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

1 INTRODUCTION

This memorandum is to amend the previous decision regarding the acceptability of the proposed proprietary name, Sunlenca, which was found conditionally acceptable under NDA 215973 and NDA 215974 on August 10, 2021.[a] We note that a conflict exists with another similar pending proposed proprietary name that is currently under review.

2 REGULATORY HISTORY

DMEPA initially reviewed the proposed proprietary name Sunlenca under IND 136260 and found the name conditionally acceptable on November 16, 2020[b]. Subsequently, we identified a conflict with another pending name under review, (b) (4) ***, and thus found the proposed proprietary name unacceptable on March 29, 2021[c].

Under NDA 215973 and NDA 215974, Gilead submitted a request for proprietary name review for Sunlenca on June 28, 2021. At the time, it appeared that Gilead's NDAs were going to be approved before the application for the conflicting name. Therefore, we found the proposed proprietary name Sunlenca conditionally acceptable for NDA 215973 and NDA 215974 on August 10, 2021[a]. However, both NDAs received a Complete Response letter on February 28, 2022.

3 DISCUSSION

Considering that NDA 215973 and NDA 215974 are currently under Complete Response status, the previously identified conflict with the pending name (b) (4) remains. The proposed name,

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[a] Fanari, M. Proprietary Name Review for Sunlenca (NDA 215973). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 Aug 10. Nexus No. 2021-1044724041 and 2021-1044724042.

[b] Vaughan, V. Proprietary Name Review for Sunlenca (NDA 215973). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Nov 16. Panorama No. 2020-40205528.

[c] Mena-Grillasca, C. Proprietary Name Review for Sunlenca (IND 136260). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Mar 29. Panorama No. 2020-40205528-1.

Sunlenca, could result in medication errors due to confusion with (b) (4)***. The rationale for the risk of confusion is described in OSE Review #2020-40205528-1 and also below.

Sunlenca vs. (b) (4)***

(b) (4)

[d] Institute for Safe Medication Practices. 2014 Jun 19. Safety briefs: Similar drug names confused. ISMP Med Saf Alert Acute Care. 19(12):1-3.

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(b) (4)

4 CONCLUSION

The proposed proprietary name is not acceptable from a safety perspective. The proposed proprietary name, Sunlenca, is vulnerable to name confusion with (b) (4)***.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

4.1 COMMENTS TO GILEAD SCIENCES, INC. (GILEAD)

Your proposed name was found conditionally acceptable on August 10, 2021. Since that time, your applications received Complete Response letters. Therefore, your proposed proprietary name Sunlenca remains in conflict with another product that is currently under review. Please note that this is the same conflict that was identified during the review of your proposed name Sunlenca under IND 136260, for which we already issued a 'Transmitting Non Public Information' letter with the contact information that the other authorized representative consented to share.

Therefore, the ultimate acceptability of your proposed proprietary name, Sunlenca, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Sunlenca, you will be requested to submit another name.

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/

CARLOS M MENA-GRILLASCA
04/08/2022 12:28:41 PM

MISHALE P MISTRY
04/08/2022 12:45:06 PM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	August 9, 2021
Application Type and Number:	NDA 215973 NDA 215974
Product Name and Strength:	Sunlenca (lenacapavir) Injection: 463.5 mg/1.5 mL (309 mg/mL) Tablet: 300 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Gilead Sciences, Inc. (Gilead)
PNR ID #:	2021-1044724041 2021-1044724042
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph
DMEPA 1 Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS
OMEPRM Director:	Lubna Merchant, PharmD, MS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Sunlenca, 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. Gilead submitted an external name study, conducted by (b) (4), for this proposed proprietary name. The submitted external name study was previously reviewed under IND 136260 (see Section 1.1 below).

1.1 REGULATORY HISTORY

Gilead previously submitted the proposed proprietary name, Sunlenca*** on September 11, 2020. DMEPA found the name, Sunlenca*** acceptable on November 16, 2020[a]. However, on March 29, 2021, DMEPA found the proposed proprietary name, Sunlenca***unacceptable due to orthographic similarities and shared product characteristics with the pending name, (b) (4)*** under IND (b) (4)[b] We note that on May 27, 2021 the pending name (b) (4)*** was withdrawn.

Thus, Gilead submitted the name, Sunlenca, for review on June 28, 2021.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 28, 2021.

- Intended Pronunciation: sun-LEN-kuh
- Active Ingredient: lenacapavir
- Indication of Use: treatment of HIV-1 infection
- Route of Administration: subcutaneous, oral
- Dosage Form: Injection; Tablet
- Strength: injection: 463.5 mg/1.5 mL (309 mg/mL); tablet: 300 mg
- Dose and Frequency:

Treatment Time	
	Dosage: Initiation
Day 1	927 mg subcutaneous injection (2 x 1.5 mL injections) 600 mg orally (2 x 300 mg tablets)
Day 2	600 mg orally (2 x 300 mg tablets)

[a] Vaughan, V. Proprietary Name Review for Sunlenca (IND 136260). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Nov 16. Panorama No. 2020-40205528.

[b] Mena-Grillasca, C. Proprietary Name Review for Sunlenca (IND 136260). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Mar 29. PNR ID No. 2020-40205528-1.

	Dosage: Maintenance
Every 6 Months (26 weeks) +/-2 weeks	927 mg subcutaneous injection (2 x 1.5 mL injections)

- How Supplied:

Injection: packaged in a dosing kit containing:

- 2 single-dose clear glass vials, each containing sufficient volume to allow withdrawal of 463.5 mg/1.5 mL (309 mg/mL) of lenacapavir. Vials are sealed with a stopper and aluminium overseal with flip-off cap.

- 2 vial access devices, 2 disposable syringes, and 2 injection safety needles for subcutaneous injection (22-gauge, ½ inch).

Tablets: packaged in a blister pack containing 4 tablets. Each tablet contains 300 mg of lenacapavir.

- Storage: Both formulations (i.e. oral loading dose and subcutaneous injection) of this product should be stored (b) (4).

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Sunlenca would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Antivirals (DAV) concurred with the findings of OPDP's assessment for Sunlenca.

2.2 SAFETY ASSESSMENT

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

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

Gilead indicated in their submission that the proposed proprietary name, Sunlenca, is derived from a combination of letters which is devoid of meaning. 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.

[c] USAN stem search conducted on July 7, 2021.

2.2.3 Comments from Other Review Disciplines at Initial Review

On July 8, 2021, the Division of Antivirals (DAV) did not forward any comments or concerns relating to Sunlenca at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred twenty-nine practitioners participated in DMEPA's prescription studies for Sunlenca. 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 97 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 review[e]. 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 also evaluated previously identified names taking into account the change in the loading dose regimen. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Therefore, we identified 2 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Review Organized by Name Pair Similarity

Table 1 lists the two 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 ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	2
Low similarity name pair: combined match percentage score ≤54%	0

[d] POCA search conducted on July 7, 2021 in version 4.3

[e] Vaughan, V. Proprietary Name Review for Sunlenca (IND 136260). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Nov 16. Panorama No. 2020-40205528.

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

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

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 1 communicated our findings to the Division of Antivirals (DAV). At that time we also requested additional information or concerns that could inform our review. On insert August 6, 2021, the Division of Antivirals (DAV) stated no additional concerns with the proposed proprietary name, Sunlenca.

3 CONCLUSION

The proposed proprietary name, Sunlenca, is acceptable.

If you have any questions or need clarifications, please contact Mammah Borbor, OSE project manager, at 301-796-7731.

3.1 COMMENTS TO GILEAD SCIENCES, INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 28, 2021, 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 ≥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[g]. 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

[g] 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 ≥ 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.

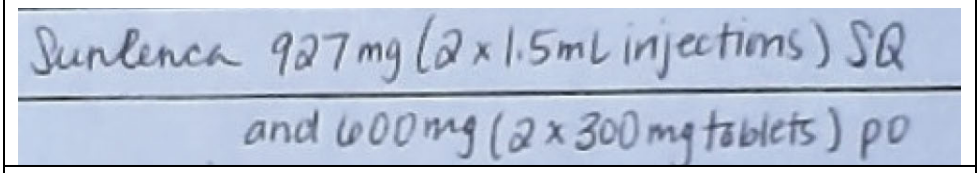
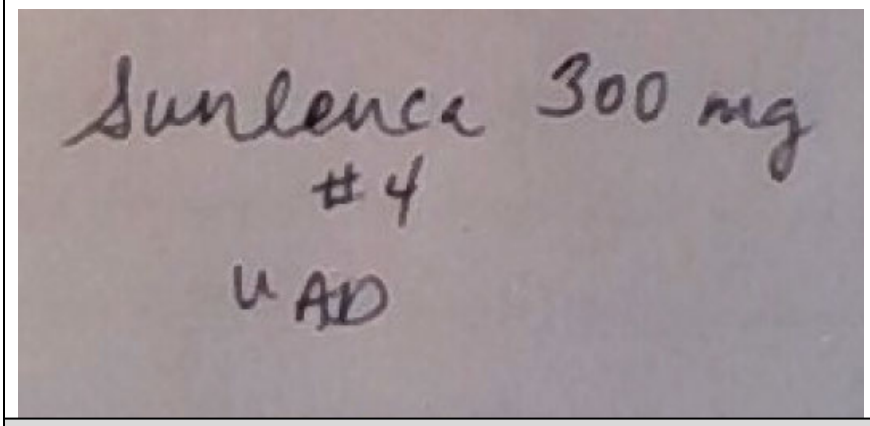
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Sunlenca Study (Conducted on August 16, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Sunlenca #4 UUD
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Sunlenca	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Sunlenca

265 People Received Study

129 People Responded

Study Name: Sunlenca

Total	29	38	30	32	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
?	0	0	1	0	1
DANLENKA	0	0	1	0	1
DONLANKA	0	0	1	0	1
DONLENTA	0	0	1	0	1
DUNLENGTA	0	0	1	0	1
DUNLINKA	0	0	1	0	1
DUNLYGA	0	0	1	0	1
DUNLYNCA	0	0	1	0	1
LYTA	0	0	1	0	1
SANGRENTA	0	0	1	0	1
SANLITA	0	0	1	0	1
SOMLINKA	0	0	1	0	1
SULENCA	1	0	0	0	1
SUMLANKA	0	0	1	0	1
SUNDENCA	1	0	0	0	1
SUNLANKA	0	0	1	0	1
SUNLECA	1	0	0	3	4
SUNLENCA	23	38	0	29	90
SUNLENCE	3	0	0	0	3
SUNLENKA	0	0	4	0	4

SUNLENTA	0	0	1	0	1
SUNLINCA	0	0	1	0	1
SUNLINCTA	0	0	1	0	1
SUNLINDA	0	0	1	0	1
SUNLINEKA	0	0	1	0	1
SUNLINKA	0	0	2	0	2
SUNLINKDA	0	0	1	0	1
SUNLYKA	0	0	1	0	1
THAMLINKA	0	0	1	0	1
THUNLENCA	0	0	1	0	1
TOMLENKA	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%)-**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.	(b) (4) ***	62

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

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤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 confusion[h].

No.	Name	POCA Score (%)
1.	(b) (4) ***	56

[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

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/

MELINA N FANARI
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SEVAN H KOLEJIAN
08/09/2021 03:25:58 PM

LUBNA A MERCHANT
08/10/2021 12:25:23 PM