

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

215344Orig1s000

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)

Date of This Review:	April 24, 2023
Application Type and Number:	NDA 215344
Product Name and Strength:	Suflave (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride) for oral solution polyethylene glycol 3350 178.7 gram, sodium sulfate 7.3 gram, potassium chloride 1.12 gram, magnesium sulfate 0.9 gram, and sodium chloride 0.5 gram
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sebela Pharmaceuticals (Sebela)
PNR ID #:	2023-1044725008
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Director:	Mishale Mistry, Pharm.D., MPH

Contents

1	INTRODUCTION	1
1.1	Regulatory History	1
1.2	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment	2
3	CONCLUSION	4
3.1	Comments to the Applicant/Sponsor	4
4	REFERENCES	5
	APPENDICES.....	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Suflave, 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. Sebela did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Sebela previously submitted the proposed proprietary name, Suflave*** under IND 134507 for review on July 12, 2021 which was found conditionally acceptable.^a Sebela submitted the name, Suflave, under NDA 215344 for review on August 6, 2021. We completed a memo on October 14, 2021 which found the name conditionally acceptable under NDA 215344.^b However, the application received a complete response (CR) on June 6, 2022 due to product quality/facility inspection deficiencies.

Sebela responded to the CR for NDA 215344 and re-submitted the proposed proprietary name, Suflave, for our review on February 23, 2023.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission and prescribing information received on February 23, 2023.

- Intended Pronunciation: soo' flave
- Active Ingredient: polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride
- Indication of Use: SUFLAVE is indicated for the cleansing of the colon as a preparation for colonoscopy in adults.
- Route of Administration: oral
- Dosage Form: for oral solution
- Strength: polyethylene glycol 3350 178.7 gram, sodium sulfate 7.3 gram, potassium chloride 1.12 gram, magnesium sulfate 0.9 gram, and sodium chloride 0.5 gram
- Dose and Frequency:
Dose 1: Evening before colonoscopy, mix and drink the contents of one of bottle (one liter).

^a Abraham, S. Proprietary Name Review for Suflave (IND 134507). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 JUL 12. PNR ID No 2021-1044723787

^b Abraham, S. Proprietary Name Review for Suflave (NDA 215344). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 OCT 14. PNR ID No 2021-1044724108

Dose 2: 5 to 8 hours before colonoscopy and at least 4 hours after dose 1, mix and drink the contents of the second bottle (one liter).

- How Supplied: The drug product is supplied in two (b) (4) bottles, each with a sachet containing acids and sweetener.
- Storage: The drug product should be stored at 25°C (77°F). Excursions permitted between 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, Suflave.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Suflave 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 Suflave. The Division of Gastroenterology (DG) concurred with the findings of OPDP's assessment for Suflave.

2.2 SAFETY ASSESSMENT

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

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

Sebela did not provide a derivation or intended meaning for the proposed proprietary name, Suflave, in their submission. This proprietary name is comprised of a single word. We note that Suflave includes the letter string '-la-', a medical abbreviation for "long-acting". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the location of the abbreviation, '-la-', in the infix of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, in this case, we do not object to the inclusion of the letter strings '-la-' in the infix of the proposed proprietary name.

2.2.3 Comments from Other Review Disciplines at Initial Review

On March 8, 2023, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Suflave at the initial phase of the review.

^c USAN stem search conducted on March 13, 2023.

2.2.4 FDA Name Simulation Studies

Eighty-nine (n=89) practitioners participated in DMEPA's prescription studies for Suflave. 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 73 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 four 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 $\geq 70\%$	1
Moderately similar name pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$	3
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 four names contained in Table 1 determined none of the names will pose a risk for confusion with Suflave as described in Appendices C through H.

^d POCA search conducted on March 13, 2023 in version 5.2.

2.2.8 Communication of DMEPA's Determination

On April 24, 2023, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

3 CONCLUSION

The proposed proprietary name, Suflave, is conditionally acceptable.

If you have any questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

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. 6F^e

^e 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,

Cerner RxNorm, 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^{7f}. 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

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

or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, 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 $\geq 70\%$).

Orthographic Checklist		Phonetic Checklist	
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.

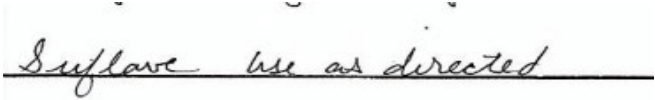
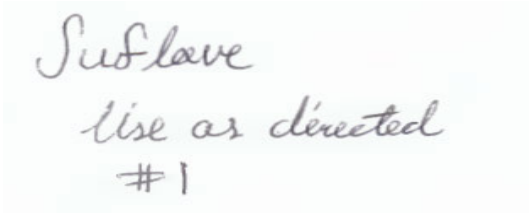
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 as 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. Suflave Study (Conducted on March 21, 2023)

Handwritten Medication Order/Prescription	Verbal Prescription
<u>Medication Order:</u> 	Suflave Use as directed #1
<u>Outpatient Prescription:</u> 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Suflave	

FDA Prescription Simulation Responses (Aggregate Report)

257 People Received Study
89 People Responded

Study Name: Suflave

Total	24	23	22	20	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
SOUFLAVE	0	0	1	0	1
SUFLAV	0	0	4	0	4
SUFLAVE	14	23	15	19	71
SUFLEEVE	0	0	0	1	1
SUFLEVE	0	0	1	0	1
SUFLOVE	6	0	0	0	6
SUIFLOVE	1	0	0	0	1
SULFAVE	2	0	0	0	2

SULFLOVE	1	0	0	0	1
SUPHLAV	0	0	1	0	1

APPEARS THIS WAY ON ORIGINAL

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

No.	Proposed name: Suflave Established name: polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride Dosage form: for oral solution Strength(s): polyethylene glycol 3350 178.7 gram, sodium sulfate 7.3 gram, potassium chloride 1.12 gram, magnesium sulfate 0.9 gram, and sodium chloride 0.5 gram Usual Dose: <i>Dose 1: Evening before Colonoscopy: 1 bottle with flavor enhancing packet Dose 2: Morning of the Colonoscopy: 1 bottle with flavor enhancing packet</i>	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.	Suflave	100	Name subject of this review.

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: Suflave Established name: polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride Dosage form: for oral solution Strength(s): polyethylene glycol 3350 178.7 gram, sodium sulfate 7.3 gram, potassium chloride 1.12 gram, magnesium sulfate 0.9 gram, and sodium chloride 0.5 gram Usual Dose: Dose 1: Evening before Colonoscopy: 1 bottle with flavor enhancing packet Dose 2: Morning of the Colonoscopy: 1 bottle with flavor enhancing packet	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.	Suavear	60	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.	Tulaven	58	Veterinary product

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion⁹.

No.	Name	POCA Score (%)
1.	Tulieve	62

⁹ 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/

SHERLY ABRAHAM
04/24/2023 05:13:15 PM

IDALIA E RYCHLIK
04/24/2023 05:26:05 PM

MISHALE P MISTRY
04/24/2023 09:30:06 PM

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)

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

Date of This Review:	October 14, 2021
Application Type and Number:	NDA 215344
Product Name and Strength:	Suflave (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride) for oral solution
	polyethylene glycol 3350 178.7 gram, sodium sulfate 7.3 gram, potassium chloride 1.12 gram, magnesium sulfate 0.9 gram, and sodium chloride 0.5 gram
Product Type:	Multiple Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Sebela Pharmaceuticals (Sebela)
PNR ID #:	2021-1044724108
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, Pharm.D.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Suflave, which was found conditionally acceptable under IND 134507 on July 12, 2021.^a Thus, Sebela submitted the name, Suflave, under NDA 215344 for review on August 6, 2021. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we 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 proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The August 27, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Suflave.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Gastroenterology (DG). At that time we also requested additional information or concerns that could inform our review. On October 14, 2021, the Division of Gastroenterology (DG) stated no additional concerns with the proposed proprietary name, Suflave.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Suflave, is acceptable.

If you have any questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

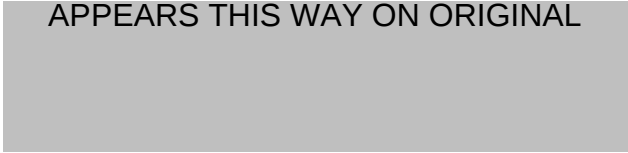
3.1 COMMENTS TO SEBELA PHARMACEUTICALS

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

^a Abraham, S. Proprietary Name Review for Suflave (IND 134507). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 JUL 12. PNR ID No 2021-1044723787

If any of the proposed product characteristics as stated in your submission, received on August 6, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

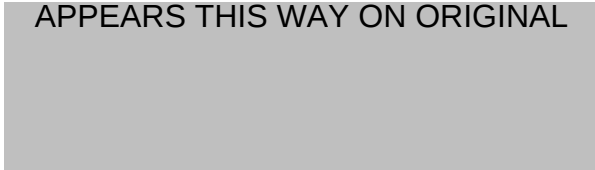


4 REFERENCE

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

USAN Stems List contains all the recognized USAN stems.

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/

SHERLY ABRAHAM
10/14/2021 11:18:41 AM

IDALIA E RYCHLIK
10/14/2021 11:38:40 AM

MISHALE P MISTRY
10/19/2021 12:20:24 PM