

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

217171Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	July 6, 2022
Application Type and Number:	NDA 217171
Product Name and Strength:	Syfovre (pegcetacoplan) injection, 15 mg/0.1 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Apellis Pharmaceuticals, Inc. (Apellis)
PNR ID #:	2022-1044724608
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD., BCPS.
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD., MPH

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Syfovre, which was found conditionally acceptable under IND 124784 on April 18, 2022.^a

Thus, Apellis submitted the name, Syfovre, under NDA 217171 for re-review on May 26, 2022. We note that there is a change in packaging for how the product will be supplied for NDA 217171. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Syfovre 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 Syfovre. The Division of Ophthalmology (DO) concurred with the findings of OPDP's assessment for Syfovre.

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. We also evaluated previously identified names taking into account the change in packaging of the product. Apellis initially proposed (b) (4). However, Apellis now proposes to package the drug product (b) (4) (i.e., each Syfovre carton will contain one single-dose, 3 mL glass vial of drug product only). Apellis also proposes to supply physician samples as an additional presentation. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Syfovre.

Additionally, we acknowledge that Syfovre contains the two-letter USAN stem '-fo-', which was assessed in our previous review. We maintain our previous conclusion that we do not object to inclusion of the two-letter USAN stem, '-fo-', incorporated into the proposed proprietary name Syfovre. Therefore, we searched the USAN stem list to determine if the proposed proprietary name contains any new USAN stems as of the last USAN updates. The June 15, 2022 search of USAN stems did not find any new USAN stems in the proposed proprietary name, Syfovre.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On July 6, 2022, we communicated our determination to the Division of Ophthalmology (DO).

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, Syfovre, is acceptable.

^a Getahun, S. Proprietary Name Review for Syfovre (IND 124784). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 APR 18. PNR ID No. 2022-1044724251.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

3.1 COMMENTS TO APELLIS PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 26, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.

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/

SOFANIT N GETAHUN
07/06/2022 10:50:03 AM

VALERIE S VAUGHAN
07/06/2022 11:52:40 AM

MISHALE P MISTRY
07/07/2022 10:06:24 AM

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)

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Date of This Review:	April 18, 2022
Application Type and Number:	IND 124784
Product Name and Strength:	Syfovre (pegcetacoplan) injection, 15 mg/0.1 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Apellis Pharmaceuticals, Inc. (Appellis)
PNR ID #:	2021-1044724251
DMEPA 1 Safety Evaluator:	Sofanit Getahun, PharmD. BCPS
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD.
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD. MPH

Contents

1	INTRODUCTION	1
1.1	Product Information.....	1
2	RESULTS.....	1
2.1	Misbranding Assessment	1
2.2	Safety Assessment	1
3	CONCLUSION	4
3.1	Comments to Apellis Pharmaceuticals, Inc.	4
4	REFERENCES.....	5
	APPENDICES	6

1 INTRODUCTION

This review evaluates the proposed proprietary name, Syfovre, 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. Appellis submitted an external name study, conducted by (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 26, 2021.

- Intended Pronunciation: sye foe' vree
- Active Ingredient: pegcetacoplan
- Indication of Use: Treatment of patients with Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD)
- Route of Administration: intravitreal
- Dosage Form: injection
- Strength: 15 mg/0.1 mL
- Dose and Frequency: 15 mg (b) (4)
- How Supplied: Vials (b) (4)
- Storage: (b) (4) (2°C to 8°C)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Syfovre would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the finding of OPDP's assessment for Syfovre. However, the Division of Ophthalmology (DO) did not respond to OPDP's assessment for Syfovre.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

The proposed proprietary name, Syfovre, contains the United States Adopted Name (USAN) stem -fo- in the infix position of the name. The USAN stem -fo- is used by the USAN Council

to indicate phosphor-derivative products.^a Proprietary names should not incorporate USAN stems in the position that USAN designates for the stem.^b The use of a USAN stem within proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names.

However, we determined that the two-letter stem ‘-fo-’ is often not distinct enough to be recognized as a USAN stem. We also note that USAN has used the stem ‘-fo-’ in established names (e.g., Fosfomycin) as well as in other USAN stems (-forant). This has resulted in conflicting stems, and therefore in those instances, the stem does not support USAN Council naming system or accurately indicate the pharmacological or chemical trait of the drug. Additionally, based on our post marketing experience we do not have the same safety concerns with the two-letter stems, including ‘-fo-,’ that we have identified with three or more letter USAN stems.^{c,d}

Therefore, we do not object to the inclusion of the two-letter USAN stem ‘-fo-,’ incorporated into the proposed proprietary name Syfovre.

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

As of February 18, 2022, the Division of Ophthalmology (DO) did not forward any comments or concerns relating to Syfovre at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred-two (102) practitioners participated in DMEPA’s prescription studies for Syfovre. 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. However, one participant in the inpatient study group commented “*depending on handwriting of prescriber, [the name] could be confused with Lyrica, especially if a technician is not experienced to know the difference.*” We evaluated the name pair, Lyrica versus Syfovre, and determined that the risk

^a USAN stem search conducted on November 10, 2021.

^b Guidance for Industry: Developing Proprietary Names for Human Prescription Drug Products. Guidance December 2020. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry>.

^c Institute for Safe Medication Practices. Safety briefs: Aripiprazole or rabeprazole? ISMP Med Saf Alert Acute Care. 2003;8(8):1-3.

^d Institute for Safe Medication Practices. Safety Briefs. ISMP Med Saf Alert Acute Care. 2002;7(17):1-2.

of confusion is mitigated because of orthographic and phonetic and product characteristic differences. Orthographically, the presence of the upstroke and cross-stroke letter ‘f’ in the 3rd position in Syfovre *versus* the letter ‘r’ in the 3rd position of Lyrica as well as the rounded letter ‘o’ in the 4th position of Syfovre compared to the dotted letter ‘i’ in same position of Lyrica provide the pair sufficient orthographic differences. Phonetically, the onset of the first syllables ‘Sye’ *versus* ‘Ly,’ the second syllables ‘foe’ *versus* ‘re,’ and the third syllables ‘vree’ *versus* ‘ca’ provide the pair sufficient phonetic differences. In addition to orthographic and phonetic differences, the products differ in route of administration (intravitreal injection *versus* oral), if included on a prescription/medication order. Furthermore, there is no overlap in strength (15 mg/0.1 mL *versus* 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg, and 300 mg), frequency ((b) (4) *versus* twice or three time a day) and dosage form (injection *versus* capsule and oral solution), making it unlikely that an error would reach the patient. (See Appendix F).

Appendix B contains the results from the prescription simulation studies.

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

Our POCA search^e identified 35 names with a combined phonetic and orthographic score of $\geq 55\%$ or an individual phonetic or orthographic score $\geq 70\%$. These names are included in Table 1 below.

2.2.6 *Names Retrieved for Review Organized by Name Pair Similarity*

Table 1 lists the number of names retrieved from our POCA search, FDA Prescription Simulation Study, and (b) (4) external study. 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 $\leq 69\%$	34
Low similarity name pair: combined match percentage score $\leq 54\%$	1

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

Our analysis of the 36 names contained in Table 1 determined none of the names will pose a risk for confusion with Syfovre as described in Appendices C through H.

^e POCA search conducted on November 10, 2021 in version 4.4.

2.2.8 *Communication of DMEPA's Determination*

On April 18, 2022, DMEPA 1 communicated our determination to the Division of Ophthalmology (DO).

3 CONCLUSION

The proposed proprietary name, Syfovre, is acceptable.

If you have any questions or need clarifications, please contact Oyinlola Fashina, OSE project manager, at 301-796-4446.

3.1 COMMENTS TO APELLIS PHARMACEUTICALS, INC.

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

A request for proprietary name review for Syfovre should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on October 26, 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 55\%$ to $\leq 69\%$.

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
 - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names⁸. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
 - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign

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

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

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

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

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

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

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

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

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

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

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

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.

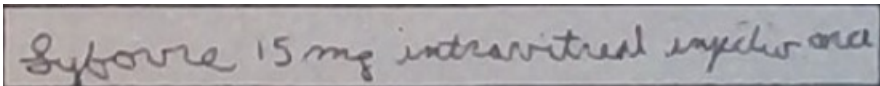
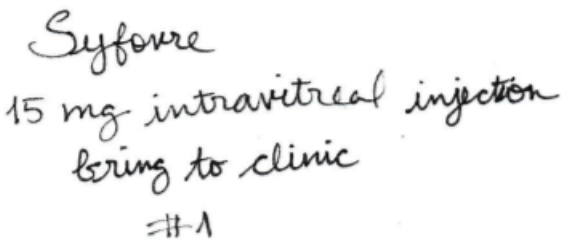
	Orthographic Checklist (Y/N to each question) - Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. - Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. - Considering variations in scripting of some letters (such as z and f), is there a different number or placement of upstroke/downstroke letters present in the names? - Is there different number or placement of cross-stroke or dotted letters present in the names? - Do the infixes of the name appear dissimilar when scripted? - Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) - Do the names have different number of syllables? - Do the names have different syllabic stresses? - Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? - Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 54\%$).

Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Syfovre Study (Conducted on November 19, 2021)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: 	Syfovre Bring to clinic for a 15 mg intravitreal injection. Disp. 1
Outpatient Prescription: 	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Syfovre	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Syfovre

263 People Received Study

102 People Responded

Total	27	20	30	25	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
CYFOVRI	0	0	2	0	2
CYFOVRY	0	0	1	0	1
CYFROVRY	0	0	1	0	1
CYPHOFERI	0	0	1	0	1
LYBOVRE	0	0	0	4	4

LYFOVRE	0	0	0	1	1
SAIFOBRI	0	0	1	0	1
SIFOVRI	0	0	1	0	1
SIFOVRY	0	0	2	0	2
SIFROVRI	0	0	1	0	1
SIPHOFRY	0	0	1	0	1
SIVOVRIE	0	0	1	0	1
SIVOVRY	0	0	1	0	1
SYBORE	0	0	0	2	2
SYBORNE	0	0	0	1	1
SYBORRE	0	0	0	4	4
SYBOURE	0	0	0	1	1
SYBOVIE	0	0	0	2	2
SYBOVRA	0	0	0	1	1
SYBOVRE	0	0	0	8	8
SYFEVRE	1	0	0	0	1
SYFOURE	5	0	0	1	6
SYFOVRE	20	20	2	0	42
SYFOVREE	0	0	1	0	1
SYFOVRI	0	0	5	0	5
SYFOVRY	0	0	2	0	2
SYFOZRI	0	0	1	0	1
SYFROFRI	0	0	1	0	1
SYFURE	1	0	0	0	1
SYPHOBRY	0	0	1	0	1
SYPHOVRY	0	0	1	0	1

SYVOFRI	0	0	1	0	1
SYVOVRI	0	0	1	0	1
ZISOFREE	0	0	1	0	1

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

No.	Proposed name: Syfovre Established name: pegcetacoplan Dosage form: injection Strength(s): 15 mg/0.1 mL Usual Dose: 15 mg intravitreal injection (b) (4)	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.	Syfovre	100	Name is 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

No.	Name	POCA Score (%)
1.	Adefovir	56

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: Syfovre Established name: pegcetacoplan Dosage form: injection Strength(s): 15 mg/0.1 mL Usual Dose: 15 mg intravitreal injection (b) (4)	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
2.	Lysodren	60	Orthographically, the presence of upstroke and cross-stroke letter 'f' in the 3 rd position in Syfovre versus the letter 's' in the 3 rd position of Lysodren and upstroke letter 'd' in the 5 th position in Lysodren versus the letter 'v' in the 5 th position of Syfovre provide the pair with sufficient orthographic differences. Phonetically, the onset of the first syllables 'Sye' versus 'Ly' and the third syllables 'vree' versus 'dren' provide the pair sufficient phonetic differences. In addition to orthographic and phonetic differences, there is no overlap in route of administration (intravitreal versus oral)

No.	Proposed name: Syfovre Established name: pegcetacoplan Dosage form: injection Strength(s): 15 mg/0.1 mL Usual Dose: 15 mg intravitreal injection (b) (4)	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
			and dosage form (injection <i>versus</i> tablet), if included on a prescription/medication order, which may help to further minimize the risk of error. When all the aforementioned mitigations are considered in totality, we find the risk of name confusion is adequately minimized in this case.
3.	Tysabri	58	This name pair has sufficient orthographic and phonetic differences.
4.	Seysara	57	This name pair has sufficient orthographic and phonetic differences.
5.	Selfemra	56	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Lyrica	22

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.	Sevoflo	64	Veterinary Product.
2.	(b) (4) ***	62	Proposed proprietary name for IND 111299 found unacceptable by DMEPA (OSE# 2019-36517463 dated June 8, 2020). NDA 214938 approved on November 19, 2021, under the proprietary name Voxzogo.
3.	S-T Forte	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	S-T Forte 2	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
5.	Zepsyre***	59	Proposed proprietary name for IND 127944 was found unacceptable by DMEPA (OSE# 2019-33148014 dated January 10, 2020). NDA 213702 was approved on June 15, 2020, under the proprietary name Zepzelca.
6.	(b) (4)***	58	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA ((b) (4)) dated (b) (4)) due to potential for confusion with another marketed name. IND (b) (4) is in pre-submission status and no new names have been submitted.
7.	Tusso-Zr	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Schiff Move Free	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
9.	Syscor Mr	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Cytosar	56	International product currently and formerly marketed in several countries.
11.	Synovex	56	Veterinary Product.
12.	(b) (4)***	56	Proposed proprietary name for IND 111091 found to be unacceptable (OSE #2017-18604320). Product approved under the proprietary name Aklied, NDA 211527.
13.	(b) (4)***	56	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA due to potential for confusion with another marketed name, ((b) (4)). Subsequently, the proposed proprietary name (b) (4)*** was found conditionally acceptable for IND (b) (4)

No.	Name	POCA Score (%)	Failure preventions
14.	Vasebra***	56	Proposed proprietary name found unacceptable on December 23, 2016, under IND (b) (4) (Panorama #: (b) (4)), due to potential for confusion with another marketed name and a pending proprietary name. Subsequently, proposed proprietary name, Edsivo***, was submitted for review and found conditionally acceptable on July (b) (4) under IND (b) (4) (Panorama #: (b) (4)), and then found unacceptable, due to potential for confusion with another pending proprietary name on January 17, 2019, under NDA (b) (4) (Panorama #: (b) (4)). NDA (b) (4) received a complete response on June 24, 2019.
15.	Zyfel	56	Brand discontinued with no generic equivalents available. ANDA 090468 withdrawn FR effective March 26, 2018.
16.	Symmetry	55	This is a family tradename for multiple topical products (e.g., Symmetry Non-Alcohol Foaming Hand Sanitizer, Symmetry Foaming Hand Sanitizer, Symmetry Hair, Hand & Foaming Wash, Symmetry Moisturizing Hand Lotion, and others). The products are marketed for use in facilities such as schools, hospitals, factories, restaurants, retail, and others. Thus, it is unlikely a prescription would be written for one of these products.
17.	Tds Forte	55	Name was found on Rx Norm. Unable to find product characteristics in commonly used drug databases.

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.	Zyflo Cr	57
2.	Fasenra	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

No.	Name	POCA Score (%)
3.	(b) (4) ***	56
4.	Vyfemla	56
5.	Isovue 370	55
6.	Isovue-128	55
7.	Isovue-200	55
8.	Isovue-250	55
9.	Isovue-300	55
10.	Isovue-370	55
11.	Myfembree	55

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/s/

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