CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761339Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

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:	5/30/2023
Responsible OND Division:	Division of Gastroenterology (DG)
Application Type and Number:	IND 142063
	BLA 761339
Product Name and Strength:	Veopoz (pozelimab-bbfg) injection
	400 mg/2 mL (200 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Regeneron Pharmaceuticals, Inc. (Regeneron)
FDA Received Date:	June 24, 2022 (IND)
	December 20, 2022 (BLA)
Nexus NPNS ID #:	2022-116 (IND)
	2022-161 (BLA)
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 1 Acting Director:	Irene Z Chan, PharmD, BCPS

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by Regeneron for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761339.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On June 24, 2022 (IND) [a] and December 20, 2022 (BLA)[b], Regeneron submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product. Table 1 presents a list of suffixes submitted by Regeneron:

Table 1. Suffixes submitted by Regeneron***

1.	bbfg
2.	(b) (4)
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

[a] Request for FDA Feedback – Nonproprietary Name Suffix Designation IND 142063. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2022 Jun 24. Available from: \\CDSESUB1\EVSPROD\ind142063\0056\m1\us\112-other-correspondence\req-comm-suffix-pozelimab.pdf

[b] Four letter Suffix Submission BLA 761339. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2022 Dec 20. Available from: \\CDSESUB1\EVSPROD\bla761339\0002\m1\us\112-other-correspondence\req-comm-suffix.pdf

We reviewed Regeneron's proposed suffixes in the order of preference listed by Regeneron, along with the supporting data they submitted, using the principles described in the applicable guidance.[a]

2.1 pozelimab-bbfg

Regeneron's first proposed suffix, -bbfg, is comprised of 3 distinct letters (b, f, g).

We determined that the proposed suffix -bbfg, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

3 COMMUNICATION OF DMEPA 1 ANALYSIS

These findings were shared with OPDP. On May 26, 2023, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA 1 also communicated our findings to the Division of Gastroenterology (DG) on May 30, 2023.

4 CONCLUSION

We find Regeneron's proposed suffix -bbfg acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to pozelimab-bbfg. DMEPA 1 will communicate our findings to the Applicant via letter.

4.1 Recommendations for Regeneron Pharmaceuticals, Inc.

We find the nonproprietary name, pozelimab-bbfg, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, pozelimab-bbfg will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we will inform you of our findings.

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[a] Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/

CARLOS M MENA-GRILLASCA
05/30/2023 11:22:02 AM

IRENE Z CHAN
05/30/2023 11:50:43 AM

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

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Date of This Review:	May 5, 2023
Application Type and Number:	IND 142063 and BLA 761339
Product Name and Strength:	Veopoz (pozelimab-xxxx)[a] injection 400 mg/2 mL (200 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals Inc. (Regeneron)
PNR ID #:	2022- 1044724639 (IND 142063) 2022- 1044724836 (BLA 761339)
DMEPA Division Director:	Mishale Mistry, PharmD, MPH

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "pozelimab-xxxx" throughout this review in place of the nonproprietary name for this product.

1 REASON FOR REVIEW

The memorandum is written because DMEPA management disagrees with some of Dr. Abraham's position with respect to the acceptability of the proposed proprietary name, Veopoz for pozelimab-xxxx injection (IND 142063 and BLA 761339), and we describe the points of disagreement below. This memorandum is intended to summarize DMEPA's overall decision based on our evaluation of the review (PNR ID # 2022- 1044724639 (IND 142063) 2022- 1044724836 (BLA 761339)) and the proposed proprietary name requests submitted under IND 142063 on June 23, 2022 and under BLA 761339 on December 20, 2022.

2 MATERIALS REVIEWED

We reviewed the following materials:

- Review authored by Dr. Sherly Abraham (attached)
- Proposed proprietary name request for Veopoz dated December 20, 2022 and June 23, 2022
- (b) (4) External Study dated June 23, 2022

3 DISCUSSION

Dr. Abraham documents a concern that the proposed proprietary name, Veopoz, is prone to confusion with another pending proposed proprietary name that is also under review, Veozah***, due to orthographic similarity and overlapping product characteristics.

We agree based on her analysis that the names Veopoz and Veozah*** have orthographic similarity. Specifically, we agree that both names are identical in length and similar in shape. We agree that the prefixes/infixes of the names are identical (Veo), the fourth letters in the names can appear similar if scripted as downstroke letters ('p' *versus* 'z'), and the vowels ('o' *versus* 'a') in fifth position may appear similar when scripted. We also agree with her acknowledgement that despite the difference in the last letters of the name pair ('z' *versus* 'h'), this difference may not be sufficient.

With respect to product characteristics, we note that Veopoz*** is an injection indicated for adult and pediatric patients 1 years of age and older with CD55-deficient protein-losing enteropathy (PLE) (also known as CHAPLE disease). A healthcare provider (HCP) will need to determine the loading dose and maintenance doses, based on the patient's weight. Both loading and maintenance doses of Veopoz*** must be prepared and administered by an HCP, who will observe the patient for 30 minutes, following administration. Prior to first use of Veopoz***, meningococcal vaccination and possibly antibacterial drug prophylaxis are recommended for patients. In contrast, Veozah*** is indicated for treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause and is intended to be orally self-administered by the patient and likely dispensed in the outpatient setting.

Dr. Abraham notes that the products may have numerically similar doses (450 mg loading intravenous dose of Veopoz *versus* 45 mg dose of Veozah***). While we agree that there is a numerically similar dose, we note that the numerically similar dose of Veopoz is specific to a pediatric patient weighing 15 kg, as both the loading and maintenance doses are based on patient weight. Furthermore, the difference in patient populations (pediatric patient *versus* female patient with menopause) would also help to mitigate the risk of error in the instance that there is a prescription/order with the numerically similar dose. The remainder of the doses of Veopoz do not overlap with that of Veozah*** (Veopoz loading intravenous dose of 30 mg/kg; Veopoz maintenance dose of (b) (4) *versus* Veozah*** dose of 45 mg or 1 tablet). Dr. Abraham also states that the products are available in a single strength and dosage form, which may not be included on a prescription/order to help differentiate the products. While we agree that these product characteristics may not be included on a prescription/order, we also note that there is no overlap in the routes of administration between the products (intravenous loading dose or subcutaneous maintenance doses *versus* oral), which should be specified on a prescription/order for Veopoz. Furthermore, the frequency of administration also differs between the products (weekly vs. daily).

In summary, we disagree with Dr. Abraham's conclusion regarding the overall acceptability of the proprietary name, Veopoz. We carefully considered Dr. Abraham's position, and when considered independently, we agree with her assessment of each point. However, when all of the mitigations are considered in totality, in this particular case, we find the risk of name confusion is mitigated to an acceptable level. We reviewed the remainder of her evaluation and did not identify any outstanding concerns.

4 CONCLUSIONS AND RECOMMENDATIONS

We conclude that the proposed proprietary name, Veopoz, is conditionally acceptable.

Given that the pending proposed proprietary name, Veozah***, was reviewed by the Division of Medication Error Prevention 2 (DMEPA 2), we sought alignment with DMEPA 2 on the acceptability of the name pair. Alignment was achieved on May 3, 2023 that the risk of name confusion is mitigated to an acceptable level.

Therefore, we recommend that this decision be conveyed to the applicant.

4.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on December 20, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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:	May 5, 2023
Application Type and Number:	IND 142063 and BLA 761339
Product Name and Strength:	Veopoz (pozelimab-xxxx)[b] injection, 400 mg/2 mL (200 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Regeneron Pharmaceuticals Inc. (Regeneron)
PNR ID #:	2022- 1044724639 (IND 142063) 2022- 1044724836 (BLA 761339)
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia Rychlik, Pharm.D.

[b]The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "pozelimab-xxxx" throughout this review in place of the nonproprietary name for this product.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Veopoz, 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. Regeneron submitted an external name study, conducted by (b) (4), for this proposed proprietary name under IND 142063 and BLA 761339.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission under IND 142063 on June 23, 2022, and prescribing information received under BLA 761339 on December 20, 2022.

- Intended Pronunciation: Vee-oh-poz
- Nonproprietary Name: pozelimab-xxxx
- Indication of Use: Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.
- Route of Administration: intravenous (loading dose) and subcutaneous (maintenance dose)
- Dosage Form: injection
- Strength: 400 mg/2 mL (200 mg/mL)
- Dose and Frequency: The recommended dosing regimen in adult and pediatric patients 1 year of age and older consists of a loading dose of Veopoz 30 mg/kg administered by intravenous infusion, followed by body weight-based once-weekly subcutaneous (SC) maintenance dosing starting 1 week after the intravenous infusion loading dose.

  (b) (4)
- How Supplied: carton containing one single-dose glass vial.
- Storage: 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Do not freeze or shake.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

Regeneron did not provide a derivation or intended meaning for the proposed proprietary name, Veopoz, in their submission. This proprietary name is comprised of a single word. We note that the proposed name Veopoz contains the letter strings, "-po-", which is the abbreviation for 'by mouth' or 'orally'. Although we typically discourage the inclusion of medication abbreviations in proprietary name, we determined that the location of the letter string, '-po-', positioned in the middle of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion in this case. Beyond this abbreviation, we note that Veopoz does not contain any additional components (i.e., modifier, route of administration, dosage form etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, January 17, 2023 e-mail, DG raised concerns about the orthographic and phonetic similarities between the proposed name, Veopoz and the proper name vedolizumab, as well as their overlapping product characteristics. DG stated that [Veopoz] is too similar to "vedolizumab" which is often referred to as "Vedo" and that "*[Veopoz] appears somewhat similar [to vedo], and both are IV infusions used for indications that may include bad diarrhea."* We evaluate the name pair below and in Appendix E.

We typically do not consider the risk of name confusion with shorthand drug name abbreviations in our evaluation of proprietary names. Furthermore, we note that the Institute of Safe Medication Practices (ISMP) and the Agency have issued warnings about the use of drug name abbreviations within the medical setting and medications are expected to be referred to by their proprietary name, generic or proper name, or both, in all verbal and written

[c] USAN stem search conducted on December 22, 2022.

communications.[d,e,f] Therefore, we evaluated the potential for name confusion between the proposed proprietary name Veopoz and DG's identified proper name, vedolizumab.

We find the name pair, Veopoz and vedolizumab, contains sufficient orthographic and phonetic differences. Orthographically, the lengths of both names differ by five letters (six letters vs. 11 letters) and the infixes/suffixes ('-opoz' vs. '-dolizumab') are different. Phonetically, the second and third syllables of the name pair sound different ('oh-poz' vs.'dol-iz') and vedolizumab has two additional syllables to pronounce. Additionally, the combined Phonetic and Orthographic Computer Analysis (POCA) score is 35%, which indicates low similarity between the name pair. Therefore, due to the above-mentioned factors, we find this name pair acceptable. We evaluated this name pair in Appendix E.

2.2.4 FDA Name Simulation Studies

Fourty-nine (n=49) practitioners participated in DMEPA's prescription studies for Veopoz. 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[g] identified 39 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥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, DG, 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 ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	34

[d] https://www.medscape.com/viewarticle/850514

[e] https://www.ismp.org/resources/confusion-error-prone-abbreviation-tpa

[f] https://www.pharmacytimes.com/view/pharmacists-shouldnt-use-tpa-abbreviations

[g] POCA search conducted on December 22, 2022 in version 5.1.

Low similarity name pair: combined match percentage score ≤54%	4

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

We determined 38 of the 39 names will not pose a risk for confusion with Veopoz as described in Appendices C through H. However, the proposed proprietary name could be confused with Veozah***. The rationale for the risk of confusion is described below:

Veopoz vs. Veozah***

The proposed proprietary name, Veopoz, may be confused with another pending proposed proprietary name that is also under review, Veozah***, due to orthographic similarity and overlapping product characteristics. Veopoz is indicated for treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

Orthographically, Veopoz and Veozah*** are identical in length (6 letters) and similar in shape. The prefixes/infixes of the names are identical (Veo). The fourth letters in the names are both downstroke letters ('p' *versus* 'z') which may appear similar when scripted. Additionally, the vowels ('o' *versus* 'a') in fifth position may appear similar when scripted. We acknowledge that Veozah*** has an upstroke letter 'h' in its last position which is absent in Veopoz and the letter 'z' in Veopoz maybe written with a downstroke; however, given the overall orthographic similarity of the of the name, these differences may not be sufficient to mitigate the risk of confusion.

The similarity of this name pair is further supported by FDA's Phonetic and Orthographic Computer Analysis (POCA) program[h], which calculates a combined orthographic and phonetic score of 60% (individual orthographic score of 71%).

In addition to orthographic similarities, Veopoz and Veozah*** share overlapping product characteristics, which further increase the potential for wrong drug errors. The loading intravenous weight-based dosing of Veopoz for a 15 kg pediatric patient is 450 mg which has a numerical similarity with the dose of Veozah*** (45 mg). We note that Veopoz and Veozah*** are available in a single strength [400 mg/2 mL (200 mg/mL) *versus* 45 mg]. Post marketing evidence suggest that the strength may be omitted if the product is only available as a single strength.[i] Therefore, the strength may not be included on a prescription to help differentiate the products. We also note that the products are available in a single dosage form (injection vs.

[h] POCA search conducted December 22, 2022 in version 5.1.

[i] Institute for Safe Medication Practices. Safety briefs: Vitamin D-angerous? ISMP Med Saf Alert Community/Ambulatory Care. 2012; 11(11): 1-4

tablets). Therefore, the dosage form may not be included on a prescription to help differentiate the products. We acknowledge that Veopoz and Veozah*** have different routes of

administration (subcutaneous/intravenous *versus* oral) and frequency of administration (once weekly versus once daily). However, we are concerned that these differences may not prevent confusion between this name pair given the orthographic similarity of the name pair in addition to the overlapping product characteristics. For example, name confusion has been reported between Advair (fluticasone and salmeterol inhalation powder) and Advicor (niacin and lovastatin tablet) despite their differences in dosage form (inhalation powder vs. tablet), route of administration (oral inhalation vs. oral), and frequency of administration (twice daily vs. at bedtime).[j] We recognize that the products have different indications (pediatric and adult treatment of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease vs. adult women for treatment of moderate to severe vasomotor symptoms (VMS) associated with menopause); however, we are concerned that this difference in indication may not prevent confusion. Despite widespread recommendations only a small percentage of medications ordered include the indication.[k] We are aware of postmarket reports of errors involving confusion between similarly named drug products, even when there is no overlap in indication, frequency, route of administration and both have single dosage forms. For example, name confusion has been reported between Cerebyx and Celebrex despite their differences in indication (treatment of generalized tonic-clonic status epilepticus and prevention and treatment of seizures occurring during neurosurgery vs. NSAID for Osteoarthritis, Rheumatoid Arthritis, acute pain treatment and dysmenorrhea), frequency (once vs. twice daily), dosage form (injection vs. capsule) and route of administration (intravenous infusion/intramuscular vs. oral).[l]

Furthermore, we acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external study.

Therefore, based on the totality of the information above, we find the proposed proprietary name, Veopoz, vulnerable to medication errors due to name confusion with Veozah***.

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[j] Institute for Safe Medication Practices. 2005 Apr. Safety Briefs: Drug must match diagnosis. ISMP Med Saf Alert Community/Ambulatory Care. 4(4):2-3

[k] Schiff GD Mirica MM, Dhavle AA, Galanter WL, Lambert B, Wright A. A Prescription for Enhancing Electronic Prescribing Safety. Health Affairs 2018; 37(11): 1877-1883.

[l] Institute for Safe Medication Practices. 1999 FEB 10. Safety Briefs. ISMP Med Saf Alert Acute Care. 4(3)2.

2.2.8 Communication of DMEPA's Determination

On May 5, 2023, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

3 REVIEWER'S CONCLUSION

The proposed proprietary name, Veopoz, is not acceptable from a safety perspective. The proposed proprietary name, Veopoz, is vulnerable to name confusion with Veozah***. Therefore, the decision to deny the name will be communicated to Regeneron via letter (See Section 3.1).

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

3.1 REVIEWER'S COMMENTS REGARDING THE PROPOSED PROPRIETARY NAME

We have completed our review of the proposed proprietary name, Veopoz, and have concluded that this name is unacceptable. The proposed proprietary name, Veopoz, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Veopoz, 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 Veopoz, you will be requested to submit another name.

We acknowledge that our conclusion differs from that of the (b) (4) external study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the (b) (4) external study.

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[m]

[m] 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 names7F[n]. 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

[n] 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 ≥ 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 <u>with</u> overlapping or similar strengths or doses.

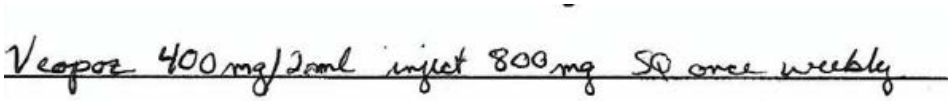
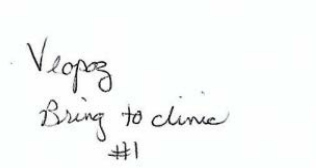
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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. Veopoz Study (Conducted on December 29, 2022)

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

FDA Prescription Simulation Responses (Aggregate Report)

259 People Received Study

90 People Responded

Study Name: Veopoz

Total	22	25	19	24	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
DIOPAUSE	0	0	1	0	1
VEALPAZ	0	0	1	0	1
VEOPAZ	0	0	4	6	10
VEOPOC	2	0	0	0	2
VEOPOR	5	0	0	0	5

VEOPOZ	11	25	0	13	49
VEPOZ	0	0	0	1	1
VESPOC	1	0	0	0	1
VESPOR	2	0	0	0	2
VESPOZ	1	0	0	0	1
VIALPAZ	0	0	1	0	1
VIAPAZ	0	0	1	0	1
VIOPAS	0	0	1	0	1
VIOPAUS	0	0	1	0	1
VIOPAZ	0	0	9	0	9
VLOPAZ	0	0	0	2	2
VLOPOZ	0	0	0	2	2

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

No.	Proposed name: Veopoz Established name: pozelimab-xxxx Dosage form: injection Strength(s): 400 mg/2 mL (200 mg/mL) Usual Dose[o]:	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.	Veopoz	100	Name subject of 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-N/A

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

No.	Proposed name: Veopoz Established name: pozelimab-xxxx Dosage form: injection Strength(s): 400 mg/2 mL (200 mg/mL) Usual Dose[o]:	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.	Compoz	60	This name pair has sufficient orthographic and phonetic differences
2.	Byooviz	58	This name pair has sufficient orthographic and phonetic differences

[o] The recommended dosing regimen in adult and pediatric patients 1 year of age and older consists of loading dose of Veopoz 30 mg/kg administered by intravenous infusion, followed by body weight-based once-weekly subcutaneous (SC) maintenance dosing starting 1 week after the intravenous infusion loading dose.

(b) (4)

No.	Proposed name: Veopoz Established name: pozelimab-xxxx Dosage form: injection Strength(s): 400 mg/2 mL (200 mg/mL) Usual Dose[o]:	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
3.	Vosol	57	This name pair has sufficient orthographic and phonetic differences
4.	Vituz	56	This name pair has sufficient orthographic and phonetic differences
5.	Vubezza	56	This name pair has sufficient orthographic and phonetic differences
6.	Vimovo	56	This name pair has sufficient orthographic and phonetic differences.
7.	Vexol	56	This name pair has sufficient orthographic and phonetic differences
8.	Zeposia	55	This name pair has sufficient orthographic and phonetic differences
9.	Vedolizumab	35	Orthographically, the lengths of both names differ by five letters (six letters vs. 11 letters) and the infixes/suffixes (‘-opoz‘ vs. ‘-dolizumab’) are different. Phonetically, the second and third syllables of the name pair sound different (‘oh-poz’ vs.’dol-iz’) and vedolizumab has two additional syllables to pronounce. Additionally, the combined Phonetic and Orthographic Computer Analysis (POCA) score is 35%, which indicates low similarity between the name pair. Therefore, due to the above-mentioned factors, we find this name pair acceptable.

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

No.	Name	POCA Score (%)
1.	Neotuss	53
2.	Velphoro	52
3.	Dia-Tuss	39
4.	Salonpas	38

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ****	65	Proposed name was denied in OSE RCM (b) (4) dated (b) (4). The proposed product was found acceptable under the name (b) (4) *** in OSE RCM (b) (4) .
2.	Vio-moore	62	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
3.	(b) (4) ***	62	Proposed proprietary name for NDA 216578 found unacceptable by DMEPA (OSE# 2022-1044724635 and 2021-1044724335 dated 09/08/2022). The proposed name Veozah*** was found conditionally acceptable under the name NDA 216578 (2022-1044724803) on December 1, 2022.
4.	Geopen	60	Brand discontinued with no generic equivalents available. NDA 050306 withdrawn FR effective March 20, 2020.
5.	Neopap	59	Brand discontinued with no generic equivalents available. NDA 016401 withdrawn FR effective September 13, 2021.
6.	Vopac	58	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
7.	Vet One	56	Veterinary product.
8.	Velosef 500	56	Brand discontinued with no generic equivalents available. NDA 050548 withdrawn FR effective 6/25/93.

No.	Name	POCA Score (%)	Failure preventions
9.	Velosef '250'	56	Brand discontinued with no generic equivalents available. NDA 050548 withdrawn FR effective 6/25/93.
10.	Velosef 125	56	Brand discontinued with no generic equivalents available. ANDA (b) (4) withdrawn FR effective 5/15/07.
11.	Velosef	56	Brand discontinued with no generic equivalents available. NDA 050530 withdrawn FR effective 11/5/92.
12.	Reopro	56	Name identified in RxNorm database. Product is deactivated per Redbook and no generic equivalents are available.
13.	Zavedos	56	International product marketed in Turkey, Argentina, Australia, Austria, Belgium, Brazil, Chile, China, Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Hungary, Ireland, Israel, Italy, Malaysia, New Zealand, Netherlands, Norway, Philippines, Poland, Portugal, Russia, South Africa, Singapore, Spain, Sweden, Switzerland, Thailand, UK, Ukraine, and Venezuela.
14.	Berdoz	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	(b) (4) ***	55	Proposed proprietary name for IND 117192 found unacceptable by DMEPA (OSE# 2017-18841009). NDA 210933 approved under the proprietary name Eysuvis.

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

No.	Name	POCA Score (%)
1.	Evotaz	64
2.	Feosol	60

[p] 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.	Depot	60
4.	Iopteez	58
5.	Fepron	56
6.	No Doz	56
7.	Ceptaz	56
8.	Phenadoz	56
9.	Pyopen	55
10.	Neosol	55

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
05/05/2023 12:20:09 PM

IDALIA E RYCHLIK
05/05/2023 12:54:09 PM

DANIELLE M HARRIS on behalf of MISHALE P MISTRY
05/10/2023 10:42:09 AM
Signed on behalf of Mishale Mistry