CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216665Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	March 11, 2025
Application Type and Number:	NDA 216665
Product Name, Dosage Form, and Strength:	Vykat XR (diazoxide choline) extended-release tablets, 25 mg, 75 mg, and 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Soleno Therapeutics, Inc. (Soleno)
PNR ID #:	2025-1044726251
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Vykat XR, 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. Soleno submitted an external name study, conducted by [redacted][a] for this proposed proprietary name.

1.1 REGULATORY HISTORY

Soleno initially submitted the proposed proprietary name, [redacted] under IND 132498 on October 4, 2021. We found the name, [redacted] acceptable in our review dated March 10, 2022.[b] However, on June 27, 2024 under NDA 216665 Soleno withdrew the name [redacted] and submitted the name [redacted] On September 24, 2024, we found the name, [redacted] unacceptable due to [redacted].[c] Thus, Soleno submitted the proposed proprietary name, Vykat***, for review on October 1, 2024 under NDA 216665. On November 22, 2024, we found the name, Vykat*** conditionally acceptable.[d] At the time of previous review, we provided additional comments to the Applicant in regard to the potential risk of medication errors involved with the inappropriate substitution of the currently marketed diazoxide oral suspension and Soleno's proposed extended-release tablets. Thus, we recommended that Soleno consider adding an appropriate modifier to their proposed proprietary name to further differentiate their proposed extended-release diazoxide choline product from the currently marketed diazoxide oral suspension.

Thus, Soleno withdrew the name Vykat*** and submitted the proposed proprietary name, Vykat XR, for review on January 27, 2025 under NDA 216665.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on January 27, 2025[e] and the prescribing information received on June 27, 2024.[f]

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[a] Proprietary Name Safety Summary for Vykat XR. [redacted].; 2025 Jan 24. Available from: \\CDSESUB1\EVSPROD\nda216665\0059\m1\us\118-proprietary-names\proprietary-name-20250127.pdf.

[b] Holmes, L. Proprietary Name Review for [redacted] (IND 132498). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 10. PNR ID No. 2021-1044724216.

[c] Holmes, L. Proprietary Name Review for [redacted] (NDA 216665). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Sep 24. PNR ID No. 2024-1044725865.

[d] Fanari, M. Proprietary Name Review for Vykat*** (NDA 216665). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Nov 22. PNR ID No. 2024-1044726024.

[e] Proprietary Name Withdrawal Request and Request for Proprietary Name Review (NDA 216665; Vykat XR). Redwood City (CA): Soleno Therapeutics, Inc.; 2025 Jan 27. Available from: \\CDSESUB1\EVSPROD\nda216665\0059\m1\us\12-cover-letters\cover-letter.pdf.

[f] Proposed prescribing information for PPN. Redwood City (CA): Full Applicant/Sponsor name; 2024 Jun 27. Available from: \\CDSESUB1\EVSPROD\nda216665\0001\m1\us\114-labeling\draft\labeling\draft-uspi-diazoxide-choline.pdf.

Table 1. Relevant Product Information for Vykat XR	
Intended pronunciation:	vye' kat ex ar
Active ingredient:	diazoxide choline
Indication:	(b) (4)
Dosage Form:	extended-release tablets
Strength:	25 mg, 75 mg, and 150 mg
Route of administration:	Oral
Dose and frequency:	(b) (4)
How Supplied:	

Table 1. Relevant Product Information for Vykat XR	
Storage:	Store TRADENAME tablets in a (b) (4) at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.] Keep in tightly closed container. Protect from humidity.
Reference Listed Drug:	Proglycem (diazoxide) NDA 017453 (oral suspension) and NDA 017425 (oral capsules, discontinued)

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vykat XR 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 Vykat XR. The Division of Psychiatry (DP) did not comment on the findings of OPDP's assessment for Vykat XR.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Soleno did not provide a derivation or intended meaning for the proposed proprietary name, Vykat XR, in their submission. This proprietary name is comprised of two components: 1) the root name, Vykat, and 2) the modifier, XR. Soleno did not provide a derivation or intended meaning for the proposed proprietary name, Vykat XR. On November 22, 2024, the acceptability of the proposed proprietary root name, Vykat*** was previously reviewed under NDA 216665.[h] The appropriateness of the modifier is discussed in Section 2.2.5 below. The name does not contain any components (i.e., a route of administration, dosage form, etc.) that can contribute to medication errors.

[g] USAN stem search conducted on February 3, 2025.

[h] Fanari, M. Proprietary Name Review for Vykat (NDA 216665). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Nov 22. PNR ID No. 2024-1044726024.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Psychiatry (DP) did not forward any comments or concerns relating to Vykat XR at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-nine (89) practitioners participated in DMEPA's prescription simulation studies for Vykat XR. 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 SAFETY ANALYSIS OF THE PROPOSED MODIFIER, "XR"

The proposed proprietary name, Vykat XR, is comprised of the root name, "Vykat" and the modifier "XR". Soleno proposed the modifier "XR" to denote extended-release.

We note that the Agency has determined that the product meets the criteria for an extended-release dosage form designation. Moreover, we note that products with the modifier "XR" have been approved in cases where a product is administered on an "every 12 hours", "twice daily", or "once daily" dosing schedule for an extended-release formulation. Based on the Institute for Safe Medication Practices (ISMP) List of Products with Drug Name Suffixes[i], the modifier "XR" is typically used to convey the meaning "extended-release" for products with modified-release formulations. As the proposed product will be dosed once daily, the use of the modifier "XR" is consistent with its existing meaning and is appropriate for conveying the extended-release characteristic of this product formulation.

We note that omission and oversight of modifiers is cited in literature as a common cause of medication errors.[j] In this case, there are no other products currently marketed under the root name "Vykat" that could be dispensed in error.

Therefore, we do not object to the use of the modifier "XR" for the proposed proprietary name, Vykat XR, and find that the modifier "XR" is acceptable.

2.2.6 COMMUNICATION OF DMEPA'S DETERMINATION

On March 11, 2025, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Vykat XR, is conditionally acceptable.

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[i] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf

[j] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

3.1 COMMENTS TO SOLENO THERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 27, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. *United States Adopted Names (USAN) Stems*

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-stems.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.[k]

Table 3. 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.

[k] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

Table 3. 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 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, Purple Book, 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 (Tables 4-6) 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 that 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 4).
- 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[I]. 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 are 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and 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-

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

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 OPQ 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 Safety Evaluator 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 4. 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 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?		

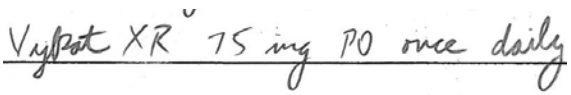
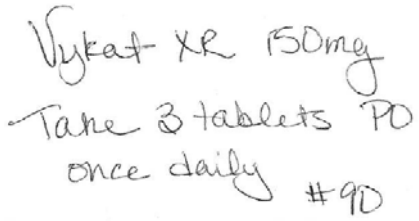
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to 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</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>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</td><td>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?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. 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. Vykat XR Study (Conducted on 2/4/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Vykat XR 150 mg Take 3 tablets by mouth once daily Dispense 90
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vykat XR	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Vykat XR People Received Study: 167 People Responded: 89					
Total	28	26	15	20	89
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
VICAP XR	0	0	1	0	1
VICAT XR	0	0	3	0	3
VIKAT XR	0	0	2	0	2
VRYLPAT XR	1	0	0	0	1
VY-CAT XR	0	0	1	0	1
VYCAT XR	0	0	4	0	4
VYKAT XR	16	26	4	20	66
VYKOT XR	1	0	0	0	1
VYKRAT XR	1	0	0	0	1
VYLPAT XR	1	0	0	0	1
VYLSAT XR	1	0	0	0	1
VYPAT XR	4	0	0	0	4
VYPOT XR	3	0	0	0	3

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/

LORETTA HOLMES
03/11/2025 04:20:42 PM

YEVGENIYA M KOGAN
03/11/2025 04:46:32 PM

IDALIA E RYCHLIK
03/12/2025 10:46:46 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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Office of Surveillance and Epidemiology (OSE)
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Date of This Review:	November 22, 2024
Application Type and Number:	NDA 216665
Product Name, Dosage Form, and Strength:	Vykat (diazoxide choline) extended-release tablets, 25 mg, 75 mg and 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Soleno Therapeutics (Soleno)
PNR ID #:	2024-1044726024
DMEPA 1 Safety Evaluator:	Melina Fanari, R.Ph.
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Soleno initially submitted the proposed proprietary name, (b) (4) under IND 132498 on October 4, 2021. We found the name, (b) (4) acceptable in our review dated March 10, 2022.[b] However, on June 27, 2024 under NDA 216665 Soleno withdrew the name (b) (4) and submitted the name (b) (4) On September 24, 2024, we found the name, (b) (4) unacceptable due to (b) (4).[c]

Thus, Soleno submitted the proposed proprietary name, Vykat, for review on October 1, 2024 under NDA 216665.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 1, 2024[d] and the prescribing information received on June 27, 2024[e].

Table 1. Relevant Product Information for Vykat	
Intended pronunciation:	Vye' kat
Active ingredient:	diazoxide choline
Indication:	(b) (4)
Dosage Form:	extended-release tablets
Strength:	25 mg, 75 mg, and 150 mg

[a] Proprietary Name Safety Summary for Vykat. (b) (4); 2024 SEPT 17. Available from: \\CDSESUB1\evsprod\NDA216665\0022\m1\us\118-proprietary-names.

[b] Holmes, L. Proprietary Name Review for (b) (4) (IND 132498). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 Mar 10. PNR ID No. 2021-1044724216.

[c] Holmes, L. Proprietary Name Review for (b) (4) (NDA 216665). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 SEPT 24. PNR ID No. 2024-1044725865.

[d] Request for Proprietary Name Review (NDA 216665; Vykat). Redwood City (CA): Soleno Therapeutics; 2024 Oct 1. Available from: \\CDSESUB1\evsprod\NDA216665\0022\m1\us\12-cover-letters.

[e] Proposed Prescribing Information for Vykat. Redwood City (CA): Soleno Therapeutics; 2024 Jun 27. Available from: \\CDSESUB1\evsprod\NDA216665\0001\m1\us\114-labeling\draft\labeling.

Table 1. Relevant Product Information for Vykat	
Route of administration:	Oral
Dose and frequency:	(b) (4)
How Supplied:	
Storage:	Store tablets in a (b) (4) at 20°C to 25°C (68°F to 77°F). [See USP Controlled Room Temperature.] Keep in tightly closed container. Protect from humidity.
Reference Listed Drug:	Proglycem (diazoxide) NDA 017453

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Vykat 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 Vykat. The Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Vykat.

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Soleno did not provide a derivation or intended meaning for the proposed proprietary name, Vykat, 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

The Division of Psychiatry (DP) expressed concerns that there is potential for confusion with Vyvanse and the proposed name, Vykat (see Appendix E).

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Ninety-five (n=95) practitioners participated in DMEPA's prescription simulation studies for Vykat. 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 31 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search, other disciplines and (b) (4) external study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	24

[f] USAN stem search conducted on October 2, 2024.

[g] POCA search conducted on October 2, 2024 in version 5.9.

Low similarity name pair: combined match percentage score ≤54%	10

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 37 names contained in Table 2 determined none of the names will pose a risk for confusion with Vykat as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On November 22, 2024, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Vykat, is conditionally acceptable.

3.1 COMMENTS TO SOLENO THERAPEUTICS

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

In addition, we have the following comments related to your product:

Your request for Proprietary Name Review states that your product will be available as an extended-release tablet. We are concerned about the risk of medication errors involving the inappropriate substitution of the currently marketed diazoxide oral solution and your extended-release tablets. We recommend you consider the addition of an appropriate modifier to your proposed proprietary name to further differentiate your proposed extended-release diazoxide choline product from the currently marketed diazoxide oral solution, which may provide an incremental measure of safety and help mitigate potential medication error vulnerabilities. Your proposed modifier should convey the extended-release properties of your product (i.e., ER or XR). If you determine that inclusion of a modifier in your proprietary name is appropriate for your product, submit your proposed name and modifier (for example, Vykat + modifier) to your NDA for review by the Agency. We request you notify the agency of your plans as early as possible in this review cycle.

If any of the proposed product characteristics as stated in your submission, received on October 1, 2024, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3*. 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.[h]

*Table 3. 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)).

[h] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. 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 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, Purple Book, 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 4-6) 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 4).

- 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[i]. 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 5).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts 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

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

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), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) 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 OPQ 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 Safety Evaluator 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 4. 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	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?

	upstroke/downstroke letters present in the names?		
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?		

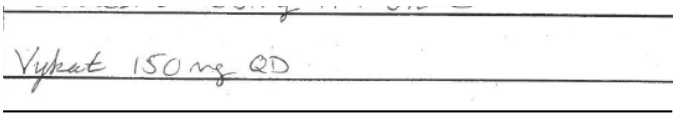
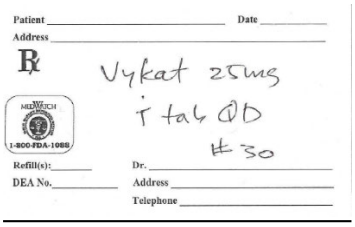
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	• 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?	• 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 6. 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. Vykat Study (Conducted on 10/25/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Vykat 25 mg 1 tablet QD #30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Vykat	

Study Name: Vykat - 2024-10-25 People Received Study: 185 People Responded: 95					
Total	21	29	19	26	95
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
BYKAT	0	1	0	0	1
VICAT	0	0	6	0	6
VICATT	0	0	1	0	1
VIKAT	0	0	2	0	2
VYCAT	0	0	6	0	6
VYKAT	16	28	4	26	74
VYKUT	5	0	0	0	5

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Vykat Pronunciation: Vye' kat Established name: diazoxide choline Dosage form: extended-release tablets Strength(s): 25 mg, 75 mg and 150 mg Dosage: 25 mg, 75 mg, 150 mg, 225 mg, 300 mg, 375 mg, 450 mg and 525 mg once daily	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.	Vykat	100	This name is the subject of this review.
2.	Zypatt	72	Veterinary product.
3.	Veta-K1	70	Veterinary product.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	Vaqta	64
2.	Vyvgart	64
3.	Voyxact***	58
4.	Mykacet	58
5.	Vytone	57
6.	Evict	55

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: Vykat Pronunciation: Vye' kat Established name: diazoxide choline Dosage form: extended-release tablets Strength(s): 25 mg, 75 mg and 150 mg Dosage: 25 mg, 75 mg, 150 mg, 225 mg, 300 mg, 375 mg, 450 mg and 525 mg once daily	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.	Ayvakit	60	This name pair has sufficient orthographic and phonetic differences.
2.	Vimpat	60	Orthographically, Vykat has a downstroke letter "y" and upstroke letters "k" in the 2nd and 3rd letter position as well as a dotted letter "i" in the 2nd position which are not present in Vimpat. Additionally, Vimpat has a downstroke letter "p" in the 4th position and a compound curve letter "m" in the 3rd position, elongating the name as compared to Vykat. These features offer some orthographic differences. Phonetically, the onset sound of the first syllables ("Vim" vs. "Vy") and the onset of the second syllable ("pat" vs. "kat") sound different.
3.	(b) (4)	58	(b) (4)
4.	Vantas	58	This name pair has sufficient orthographic and phonetic differences.
5.	(b) (4)	56	(b) (4)

No.	Proposed name: Vykat Pronunciation: Vye' kat Established name: diazoxide choline Dosage form: extended-release tablets Strength(s): 25 mg, 75 mg and 150 mg Dosage: 25 mg, 75 mg, 150 mg, 225 mg, 300 mg, 375 mg, 450 mg and 525 mg once daily	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 (b) (4)
6.	Vita #12	56	This name pair has sufficient orthographic and phonetic differences.
7.	Vyvanse	46	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Zinnat	54
2.	Vituz	52
3.	(b) (4)	50
4.	Picot	48
5.	Zicam	47
6.	Vytorin	46
7.	Xysed	46
8.	Victoza	42
9.	Deco-P	36

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.	Vkzt	62	Name identified in (b) (4) study. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4)	59	Proposed proprietary name for IND 132131 found unacceptable by DMEPA due to a conflict with a marketed product (OSE# 2020-41082750 dated 09/28/2020). NDA 217369 approved under the proprietary name Zurzuvae.
3.	Vetaket	58	Veterinary product.
4.	(b) (4)	58	Proposed proprietary name for BLA 761061 found unacceptable by DMEPA (OSE RCM # 2017-13165377 dated 04/05/2017). Subsequently, BLA 761061 was approved under the proprietary name, Tremfya, on 07/13/2017.
5.	(b) (4)	56	Proposed proprietary name withdrawn by the Applicant on (b) (4). Alternative name (b) (4) found conditionally acceptable under IND (b) (4) .
6.	Vitekta	56	Brand discontinued with no generic equivalents available. NDA 203093 withdrawn FR effective 11/02/2017.
7.	Vasad	56	International product formally marketed in the UK.

No.	Name	POCA Score (%)	Failure preventions
8.	Vigam	55	Brand discontinued with no generic equivalent available in the USA. International product marketed in numerous international countries.

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

No.	Name	POCA Score (%)
1.	Avycaz	62
2.	Dytan	58
3.	Duvyzat	56
4.	Baytet	55

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

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/s/

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11/22/2024 08:01:31 AM

YEVGENIYA M KOGAN
11/22/2024 10:24:46 AM

IDALIA E RYCHLIK
11/22/2024 10:27:05 AM

This is a corrected review that does not change the overall recommendations/conclusions of the original review dated September 24, 2024

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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

Date of This Review:	September 24, 2024
Application Type and Number:	NDA 216665
Product Name, Dosage Form, and Strengths:	(b) (4) (diazoxide choline) extended-release tablets, 25 mg, 75 mg, and 150 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Soleno Therapeutics, Inc. (Soleno)
PNR ID #:	2024-1044725865
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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/s/

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