CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

214273Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 7, 2022
Application Type and Number:	NDA 214273
Product Name and Strength:	Zonisade (zonisamide) oral suspension, 100 mg/5 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals, Inc. (Azurity)
PNR ID #:	2022-1044724400
DMEPA 2 Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA 2 Team Leader (Acting):	Stephanie DeGraw, PharmD
DMEPA 2 Director:	Danielle Harris, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Azurity previously submitted the proposed proprietary name, Zonisade on November 10, 2020. We found the name, Zonisade conditionally acceptable under NDA 214273 on February 4, 2021.[a] However, a complete response (CR) letter was issued for NDA 214273 on May 28, 2021.[b]

Subsequently, Azurity submitted a Class 2 Resubmission to NDA 214273 received on January 18, 2022.

Thus, Azurity resubmitted the name, Zonisade, for review on January 18, 2022 as part of the Class 2 Resubmission. However, the submission did not include all the product characteristics associated with the proposed proprietary name. Therefore, Azurity resubmitted the proprietary name request on January 27, 2022 for Zonisade which included all product characteristics. We note that all product characteristics remain the same from the November 10, 2020 submission.

1.2 PRODUCT INFORMATION

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

- Intended Pronunciation: Zaan-i-said
- Active Ingredient: zonisamide
- Indication of Use: adjunctive therapy in the treatment of partial seizures in adults with epilepsy.
- Route of Administration: Oral
- Dosage Form: Suspension
- Strength: 100 mg/5 mL
- Dose and Frequency: Initial dose 100 mg daily. (b) (4)

[a] Weitzman, B. Proprietary Name Review for Zonisade (NDA 214273). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2021 FEB 4. PNR ID No. 2020-43869545.

[b] Parncutt, S. Communication: Complete Response Letter for Zonisade (zonisamide) Oral Suspension. Silver Spring (MD): FDA, CDER, OND, ODEI, DNP (US); 2021 MAY 28. NDA 214273. Available via: https://darrts fda.gov/darrts/ViewDocument?documentId=090140af805f4747

- How Supplied: 150 mL amber colored PET bottle with a child-resistant cap (CRC).
- Storage: Store at 25°C (77°F), excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature], (b) (4) and protected from light. Discard any unused zonisamide oral suspension remaining 30 days after first opening of the bottle.
- Reference Listed Drug/Reference Product: Zonegran (NDA 020789)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zonisade would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Zonisade.

2.2 SAFETY ASSESSMENT

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

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

Azurity indicated in their submission that the proposed proprietary name, Zonisade is derived from a combination of the words "Zon" plus "Sade", where the word "Zon" is derived from ancient Greek and generally means buffer zone or life zone and the word "Sade" is derived from many languages and generally relates to rain or air during rain. The intended meaning of the entire proprietary name Zonisade is "to protect via buffer of rain." This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

The Division of Neurology 2 (DN 2) did not provide comments regarding Zonisade at the initial phase of the review.

[c] USAN stem search conducted on February 25, 2022.

2.2.4 FDA Name Simulation Studies

Eighty-four practitioners participated in DMEPA's prescription studies for Zonisade. 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.

Eight respondents in the inpatient/outpatient/CPOE study provided supplemental comments:

- "look alike/very similar" to zonisamide [inpatient n=3, outpatient n=1, CPOE n=1]
- "looks/sounds like" zonisamide [outpatient n=1]
- "I almost transcribed as "Zonisamide at first glance and I think this is way too close" [outpatient n=1]
- "I initially thought this was zonisamide" [outpatient n=1].

Zonisamide is the active ingredient for the proposed product, Zonisade. We evaluated the name pair, Zonisade and zonisamide, further and find zonisamide is the established name of this proposed proprietary name that is the subject of this review. Additionally, we considered that zonisamide is also the established name for Zonegran. We note that Zonisade and Zonegran share the same active ingredient, same indication, same route of administration, same dose, and same frequency of administration. Therefore, if the products were confused or inadvertently substituted one for the other the patient would receive the same medication and identical dose of the intended drug, thus minimizing the risk if the products were confused.

Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 351 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 3 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**

[d] POCA search conducted on February 25, 2022 in version 4.4.

Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	3
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 3 names contained in Table 1 determined none of the names will pose a risk for confusion with Zonisade as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On March 7, 2022, we communicated our determination to the Division of Neurology 2 (DN 2)

3 CONCLUSION

The proposed proprietary name, Zonisade, is acceptable.

If you have any questions or need clarifications, please contact Margee Webster, OSE project manager, at 240 402-0012.

3.1 COMMENTS TO AZURITY PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on January 27, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [e]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.

- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[f]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

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

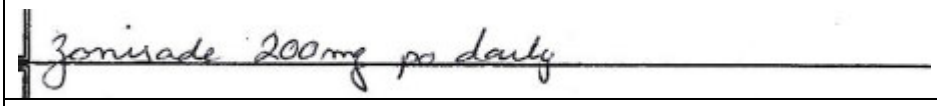
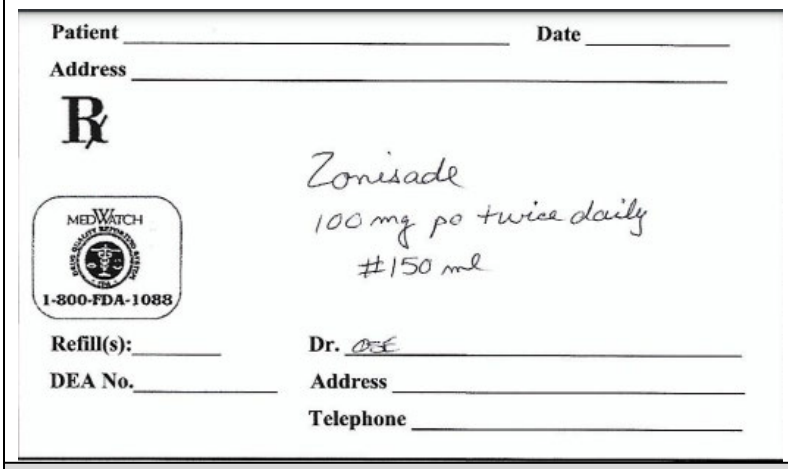
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Zonisade Study (Conducted on February 22, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Zonisade 100 mg by mouth twice daily #150 mL
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Zonisade	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
84 People Responded

Study Name: Zonisade

Total	20	23	20	21	84
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
XONASAVE	0	0	1	0	1
XUANASAID	0	0	1	0	1
ZANASADE	0	0	1	0	1

ZANIRADE	0	0	0	1	1
ZONASADE	0	0	2	0	2
ZONASAID	0	0	5	0	5
ZONASAYD	0	0	2	0	2
ZONEIADE	1	0	0	0	1
ZONESADE	0	0	1	0	1
ZONIRADE	0	0	0	5	5
ZONIRADE 200 MG	0	0	0	1	1
ZONISADE	19	23	3	12	57
ZONISAID	0	0	2	0	2
ZONISAIDE	0	0	1	0	1
ZONISAMIDE	0	0	0	1	1
ZONOSADE	0	0	1	0	1
ZONSADE	0	0	0	1	1

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

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** Suspension **Strength(s):** 100 mg/5 mL **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks (b) (4) of 400 mg/day administered once or twice 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.**
	N/A		

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
	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:** Zonisade **Established name:** zonisamide **Dosage form:** Suspension **Strength(s):** 100 mg/5 mL **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks (b) (4) of 400 mg/day administered once or twice 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**
	N/A		

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

No.	Name	POCA Score (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
	N/A		

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

No.	Name	POCA Score (%)
1.	Ponesimod	62
2.	Sabinene	58
3.	Lamzede***	56

[g] 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/

BEVERLY WEITZMAN
03/07/2022 02:40:13 PM

STEPHANIE L DEGRAW
03/07/2022 04:53:51 PM

DANIELLE M HARRIS
03/08/2022 07:37:26 AM

PROPRIETARY NAME REVIEW

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:	February 4, 2021
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Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Eton Pharmaceuticals, Inc. (Eton)
Panorama #:	2020-43869545
DMEPA Safety Evaluator:	Beverly Weitzman, PharmD
DMEPA Team Leader (Acting):	Celeste Karpow, PharmD, MPH

Contents

1 INTRODUCTION

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

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on November 10, 2020.

- Intended Pronunciation: Zaan-i-said
- Active Ingredient: zonisamide
- Indication of Use: adjunctive therapy in the treatment of partial seizures in adults with epilepsy.
- Route of Administration: Oral
- Dosage Form: suspension
- Strength: 100 mg/5 mL
- Dose and Frequency: Initial dose 100 mg daily. (b) (4)
- How Supplied: 150 mL amber colored PET bottle with a child-resistant cap (CRC).
- Storage: Store at 25°C (77°F), excursions permitted to 15–30°C (59–86°F) [see USP Controlled Room Temperature], (b) (4) and protected from light. Discard any unused zonisamide oral suspension remaining 30 days after first opening of the bottle.
- Reference Listed Drug/Reference Product: N/A

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Zonisade would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Zonisade.

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Eton indicated in their submission that the proposed proprietary name, Zonisade is derived from a combination of the words "Zon" plus "Sade", where the word "Zon" is derived from ancient Greek and generally means buffer zone or life zone and the word "Sade" is derived from many languages and generally relates to rain or air during rain. The intended meaning of the entire proprietary name Zonisade is "to protect via buffer of rain." This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, December 1, 2020 e-mail, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to Zonisade at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Eighty-five practitioners participated in DMEPA's prescription studies for Zonisade. One response from the voice study did overlap with the currently marketed product, sennosides. We evaluated the name pair, Zonisade and sennosides, further and fine there are sufficient orthographic, phonetic, and product characteristic differences.

> Orthographically, the name pair begins with different first letters (Z vs. S) that look different when capitalized. Additionally, the lengths of the names (8 letters vs. 10 letters) are dissimilar when scripted. Furthermore, Sennosides contains an additional rounded letter 'n' in the infix, which is not present in Zonisade and gives the names different shapes when scripted.
>
> Phonetically, the first syllables (Zaan vs. ˈsen) and the third syllables (said vs. sīd) sound different when spoken.
>
> Additionally, there is no direct overlap in strength (100 mg/5 mL (20 mg/mL) versus 8.6 mg), dose (100 mg up to (b) (4) 400 mg versus ½ tablet up to a maximum of 4 tablets) or dosage form (oral suspension versus tablet) which would further help differentiate the name pair if included.
>
> When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level (See appendix E).

Three respondents in the voice study interpreted the proposed proprietary name as Sunafed [n=1] and Sunased [n=2] which is a close variation to the marketed product, Sudafed. We evaluated the name pair, Zonisade and Sudafed, further and find that there are sufficient orthographic, phonetic, and product characteristic differences.

> Orthographically, the name pair begins with different first letters (Z vs. S) that look different when capitalized. Additionally, Zonisade contains the rounded letter 'n' in the

[a] USAN stem search conducted on December 5, 2020.

prefix, whereas Sudafed contains the upstroke letter 'd' in the prefix which may provide some differentiation. Furthermore, depending on how scripted, Sudafed contains the cross-stroke/downstroke letter 'f' or upstroke letter 'f' at the beginning of the suffix, which gives the names different shapes when scripted. Lastly, Zonisade contains the additional letter 'e' at the end of the suffix, which is not present in Sudafed which may provide additional differentiation of the name pair.

Phonetically, the first syllables (Zaan vs. Soo), second syllables (i vs. duh), and third syllables (said vs fed) sound sufficiently different when spoken.

Additionally, the brand name, Sudafed is a family name for an over the counter product line of cold and allergy products. These products are identified by the use of a modifier to differentiate the products. For example, Children's Sudafed Nasal Decongestant, Children's Sudafed PE, Sudafed Sinus Congestion 12 hours, Sudafed Sinus Congestion 24 hours, and Sudafed PE Congestion. A prescription would need to include specific information to identify and differentiate between the products (e.g., strength and dosage form), which will provide additional differentiation between the name pair and this family of products.

When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level (See appendix E)

Additionally, five respondents in the inpatient/outpatient study provided supplemental comments: "look alike/very similar" to zonisamide [outpatient n=3, inpatient n=1]] and "looks/sounds like" zonisamide [outpatient n=1], which is the active ingredient for the proposed product, Zonisade. We evaluated the name pair, Zonisade and zonisamide, further and find zonisamide is the established name of this proposed proprietary name that is the subject of this review. Additionally, we considered that zonisamide is also the established name for Zonegran. We note that Zonisade and Zonegran share the same active ingredient, same indication, same route of administration, same dose, and same frequency of administration. Therefore, if the products were confused or inadvertently substituted one for the other the patient would receive the same medication and identical dose of the intended drug, thus minimizing the risk if the products were confused.

Lastly, twenty-eight respondents in the voice study, misinterpreted the sound of the first letter "Z" in Zonisade as an "S". Also, one respondent in the outpatient study, misinterpreted the first letter "Z" in Zonisade as an "I". Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 348 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.

[b] POCA search conducted on December 5, 2020 in version 4.4.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and FDA Prescription Simulation 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%	5
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	328
Low similarity name pair: combined match percentage score ≤54%	16

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

Our analysis of the 349 names contained in Table 1 determined none of the names will pose a risk for confusion with Zonisade as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Neurology 2 (DN 2) via e-mail on February 3, 2021. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology 2 (DN 2) on February 4, 2021, they stated no additional concerns with the proposed proprietary name, Zonisade.

3 CONCLUSION

The proposed proprietary name, Zonisade, is acceptable.

If you have further questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

3.1 COMMENTS TO ETON PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on November 10, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

- Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
- Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html).

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

APPENDICES

Appendix A

FDA's Proprietary Name Risk Assessment evaluates proposed proprietary names for misbranding and safety concerns.

1. **Misbranding Assessment**: For prescription drug products, OPDP assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNDP. OPDP or DNDP evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment**: The safety assessment is conducted by DMEPA, and includes the following:

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [c]

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

***Table 2- Prescreening Checklist for Proposed Proprietary Name**

	Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.
Y/N	**Is the proposed name obviously similar in spelling and pronunciation to other names?**
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	**Are there inert or inactive ingredients referenced in the proprietary name?**
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	**Does the proprietary name include combinations of active ingredients?**
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	**Is there a United States Adopted Name (USAN) stem in the proprietary name?**
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	**Is this proprietary name used for another product that does not share at least one common active ingredient?**
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	**Is this a proprietary name of a discontinued product?**
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[d]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

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

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).

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

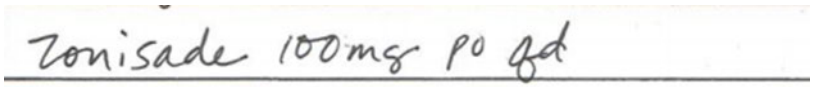
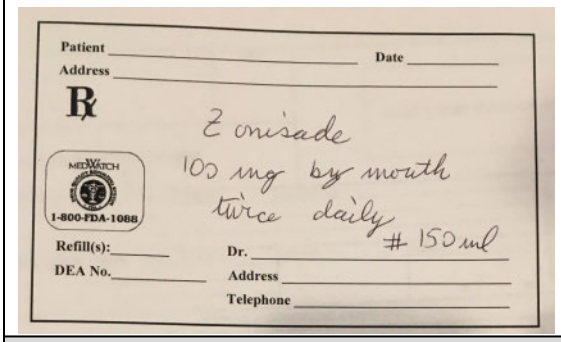
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

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

Appendix B: **Prescription Simulation Samples and Results**

Figure 1. Zonisade Study (Conducted on November 20, 2020)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Zonisade 100 mg by mouth twice daily #150 mL
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Zonisade	

FDA Prescription Simulation Responses (Aggregate Report)

209 People Received Study
85 People Responded

Study Name: Zonisade

Total	**23**	**18**	**28**	**16**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
IONISADE	0	0	0	1	1
SENNOSIDES	0	0	1	0	1
SONASAIS	0	0	1	0	1
SONASAL	0	0	1	0	1
SONASAY	0	0	1	0	1
SONASED	0	0	5	0	5
SONASET	0	0	4	0	4
SONESET	0	0	1	0	1

SONICAY	0	0	1	0	1
SONISAID	0	0	1	0	1
SONISED	0	0	1	0	1
SUNACID	0	0	2	0	2
SUNAFED	0	0	1	0	1
SUNASED	0	0	2	0	2
SUNASET	0	0	3	0	3
SUNASYD	0	0	1	0	1
SUNICED	0	0	1	0	1
SUNISED	0	0	1	0	1
ZONISADE	23	18	0	14	55
ZONISAMIDE	0	0	0	1	1

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

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg (b) (4) every two weeks to 400 mg administered once or twice 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.	Zonisade	100	Proposed proprietary name that is the subject of this review.
2.	Zonisamide	79	Zonisamide is the established name of this proposed proprietary name that is the subject of this review. Therefore, any confusion with this name pair will result in the patient getting the intended drug. Zonisamide is also the established name for Zonegran which is evaluated in Appendix E.
3.	Sonazine Note: Discontinued product with branded generic equivalents available.	72	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes (sade vs. zine) look sufficiently different. Zonisade contains the upstroke letter 'd' in the suffix, whereas Sonazine does not contain any upstroke letters. Additionally, Sonazine contains the letter 'z' in the suffix, which if scripted with a downstroke may provide additional differentiation. Phonetically, the second (i vs. ah) and third syllables (said vs. zine) provides sufficient phonetic differences. We note that Sonazine (chlorpromazine hydrochloride) is a discontinued branded generic product which was available as a syrup and concentrate. There are generics that are marketed under the established name "chlorpromazine hydrochloride",

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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.**
			however, they are not available in the same dosage forms as Sonazine (i.e., syrup and concentrate). The generic products are available as a tablet and injection. Therefore, if Sonazine drug product was prescribed, the prescription would need to be verified since those dosage forms (i.e., syrup and concentrate) are not currently available in the market place. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
4.	Zenatane	70	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes (sade vs. tane) of this name pair look sufficiently different. Zonisade contains the letter 's' in the fifth position and an upstroke letter 'd' in the seventh position, whereas Zenatane contains a cross-stroke letter 't' in the fifth position and rounded letter 'n' in the seventh position which gives the names different shapes when scripted. Phonetically, the rimes in the first syllables (/aa/ vs. /e/) and the third syllables (said vs tane) sound different when spoken. Furthermore, the following product characteristics may provide additional

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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.**
			differentiation if included: Zonisade is available in one strength (100 mg/5mL (20 mg/mL)), whereas Zenatane is available in four strengths (10 mg, 20 mg, 30 mg and 40 mg) which must be specified on the prescription and the strengths do not overlap. Additionally, there is no direct overlap in dosage form (oral suspension versus capsule). When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
5.	Sinus Aid	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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.	Lidazone	66
2.	Spinosad	64
3.	Zinacef	63
4.	Zone-A Forte	62
5.	Zinc Oxide	61
6.	Desonide	60
7.	Sonacaine	60
8.	Zonalon	60
9.	Painzone	59
10.	Zinotic ES	59
11.	Nasalide	58
12.	Na-zone	58
13.	Tokisan	58

No.	Name	POCA Score (%)
14.	Tomycine	57
15.	Zensa	57
16.	Zontivity	57
17.	Enzone	56
18.	Zionodil	56
19.	Zymaxid	56
20.	Va-zone	55
21.	Zonnic	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:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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.	Isoniazid	68	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes (zon vs. iso) and the suffixes (sade vs. azid) look sufficiently different when scripted. Additionally, Isoniazid contains the letter 'z' in the suffix, which if scripted with a downstroke may provide additional differentiation. Phonetically, Zonisade is 3 syllables whereas Isoniazid is 5 syllables. Additionally, the first (Zaan vs. Ice), second (eh vs. sow), and third (said vs. nye) syllables sound sufficiently different. Additionally, Zonisade is available in a single dosage form (oral suspension) which may be omitted, whereas isoniazid is available in three dosage

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			forms (tablet, oral solution, and injection) which must be specified on the prescription which may further help differentiate the name pair.
2.	Zinecard	68	This name pair has sufficient orthographic and phonetic differences. Orthographically, Zonisade contains the rounded letter 'o' in the second position, whereas Zinecard contains the dotted letter 'i' in the second position that look different when scripted. Additionally, Zinecard contains the letters 'c' and rounded letter 'r' in the suffix which give the names different shapes when scripted. Phonetically, the rimes of the first syllables (/aa/ vs. /i/) and the third syllables (said vs. card) sound different when spoken. Furthermore, the following product characteristics may provide additional differentiation if included: Zonisade is available in one strength (100 mg/5mL (20 mg/mL)), whereas Zinecard is available in two strengths (250 mg per vial and 500 mg per vial which must be specified on the prescription and the strengths do not overlap. Additionally, there is no direct overlap in dosage form (oral suspension versus injection) or route of administration (oral vs. intravenous infusion).

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			Additionally, Zinecard is a cardioprotectant medication intended to be administered intravenously along with doxorubicin, a chemotherapy agent which may help mitigate confusion with the name pair.
3.	Zenavod	66	Orthographically, Zonisade contains the dotted letter 'i' in the infix and the letter 's' at the beginning of the suffix, whereas Zenavod does not contain any dotted letters, and contains the letter 'v' at the beginning of the suffix which gives the name pair different shapes when scripted. Additionally, Zonisade contains the additional letter 'e' at the end of the suffix, which is not present in Zenavod and may provide some differentiation. Phonetically, the first syllables (Zaan vs. Ze), second syllables (i vs. na) and third syllables (said vs. vod) sound different when spoken. Additionally, the following product characteristics may provide additional differentiation, if included: There is no direct overlap in strength (100 mg/5 mL (20 mg/mL) versus 40 mg), dose (100 mg up to (b) (4) 400 mg versus 40 mg) or dosage form (oral suspension versus capsule).
4.	Sonidegib	64	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			Orthographically, the suffixes (sade vs. degib) look sufficiently different when scripted.
5.	Stanozide	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, Stanozide contains the cross-stroke letter 't' in the prefix, whereas Zonisade does not contain a cross-stroke letter in the prefix which gives the names different shapes when scripted. Additionally, Stanozide contains the letter 'z' in the sixth position, which if scripted with a downstroke, will provide additional differentiation. Phonetically, the second syllables (eh vs. o) and third syllables (said versus ide) sound sufficiently different. Furthermore, the following product characteristics may provide additional differentiation if included: Zonisade is available in one strength (100 mg/5mL (20 mg/mL)), whereas Stanozide is available in two strengths (100 mg and 300 mg) which must be specified on the prescription and the strengths do not overlap. Additionally, there is no direct overlap in dosage form (oral suspension versus tablet).
6.	Vibisone	64	This name pair has sufficient orthographic and phonetic differences. Phonetically, the first syllables (Zaan vs. Vib) and rimes of the third syllables

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to [redacted] (b) (4) 400 mg administered once or twice 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**
			(/ai/ vs. /on/) sound different when spoken.
7.	Xenazine	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, the name pair begins with different first letters (Z vs. X) that look different. Additionally, Zonisade contains the upstroke letter 'd' in the suffix, whereas Xenazine does not contain any upstroke letters, which gives the names different shapes when scripted. Lastly, Xenazine contains the letter 'z' in the fifth position, which if scripted with a downstroke will provide additional differentiation. Phonetically, the rimes of the first syllables (/aa/ vs /ee/) and the third syllables (said vs. zine) sound different when spoken. Furthermore, the following product characteristics may provide additional differentiation, if included: Zonisade is available in one strength (100 mg/5mL (20 mg/mL)), whereas Xenazine is available in two strengths (12.5 mg and 25 mg) which must be specified on the prescription and the strengths do not overlap. Additionally, there is no direct overlap in dose (100 mg up to a [redacted] (b) (4) 400 mg versus 12.5 mg up to a maximum dose of 50 mg) or dosage form (oral suspension versus tablet).

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
8.	Ziconotide	64	This name pair has sufficient orthographic and phonetic differences. Orthographically, Zonisade contains 8 letters whereas Ziconotide contains 10 letters, giving the names a different length. Additionally, Zonisade contains the rounded letter 'o' in the 2nd position and the letter 's' in the 5th position and does not contain any cross-stroke letters, whereas Ziconotide contains the dotted letter 'i' in the 2nd position and the cross-stroke letter 't' in the 5th position which provides sufficient differentiation. Furthermore, the infixes of this name pair look sufficiently different (i vs. cono), which gives the names different shapes when scripted.
9.	Docusate	63	This name pair has sufficient orthographic and phonetic differences. Phonetically, the first syllables (DOK vs. Zaan) sound different when spoken.
10.	Fernisone	63	This name pair has sufficient orthographic and phonetic differences.
11.	Zincate	63	This name pair has sufficient orthographic and phonetic differences.
12.	Ansaid	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, the name pair begins with different first letters (A vs. Z) that look different. Additionally, the lengths of the names (8 letters vs. 6 letters) are dissimilar when scripted.

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			Lastly, Zonisade contains the additional letter 'e' at the end of the suffix, which is not present in Ansaid, which may provide additional differentiation. Phonetically, Zonisade is 3 syllables whereas Ansaid is only 2 syllables. Additionally, the first syllables (Zaan vs. An) and second syllables (eh vs. aid) sound sufficiently different.
13.	Loniten	62	This name pair has sufficient orthographic and phonetic differences.
14.	Monistat	62	This name pair has sufficient orthographic and phonetic differences.
15.	Monistat 3	62	This name pair has sufficient orthographic and phonetic differences.
16.	Monistat 7	62	This name pair has sufficient orthographic and phonetic differences.
17.	Monistat-1	62	This name pair has sufficient orthographic and phonetic differences.
18.	Remicade	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, the prefixes (Rem vs. Zon) look sufficiently different when scripted. Phonetically, the first syllables (Zaan vs. Rem), second syllables (eh vs. i) and the onset of the third syllables (sade vs. cade) sound different when spoken. Additionally, there is no direct overlap in dosage form (oral suspension versus for injection), route of administration

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			(oral vs. intravenous infusion) or frequency (once or twice daily vs. induction regimen at 0, 2, 6 weeks followed by maintenance dose every 8 weeks) which would further help differentiate the name pair if included. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
19.	Sennosides	62	This name pair has sufficient orthographic and phonetic differences. Orthographically, the name pair begins with different first letters (Z vs. S) that look different when capitalized. Additionally, the lengths of the names (8 letters vs. 10 letters) are dissimilar when scripted. Furthermore, Sennosides contains an additional rounded letter 'n' in the infix, which is not present in Zonisade, and gives the names different shapes when scripted. Phonetically, the first syllables (Zaan vs. Sen) and the third syllables (said vs. sīd) sound different when spoken. Additionally, there is no direct overlap in strength (100 mg/5 mL (20 mg/mL) versus 8.6 mg), dose (100 mg up to a (b) (4) 400 mg versus ½ tablet up to a maximum of 4 tablets) or dosage form (oral suspension versus

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			tablet) which would further help differentiate the name pair if included. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
20.	Cenafed	61	This name pair has sufficient orthographic and phonetic differences. Phonetically, the first syllables (Zaan vs. Cen) and the third syllables (said vs. fed) sound different when spoken. Additionally, Cenafed is a discontinued brand of pseudoephedrine hydrochloride (30 mg/5 mL) oral solution and (60 mg) tablets that would likely be prescribed by the better-known brand name, Sudafed, or the established name pseudoephedrine hydrochloride.
21.	Adenosine	60	This name pair has sufficient orthographic and phonetic differences.
22.	Bicisate	60	This name pair has sufficient orthographic and phonetic differences.
23.	Budesonide	60	This name pair has sufficient orthographic and phonetic differences.
24.	Genaphed	60	This name pair has sufficient orthographic and phonetic differences.
25.	onivyde	60	This name pair has sufficient orthographic and phonetic differences.
26.	Somnicin	60	This name pair has sufficient orthographic and phonetic differences.
27.	Sudafed	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to a (b) (4) 400 mg administered once or twice 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**
			Orthographically, the name pair begins with different first letters (Z vs. S) that look different when capitalized. Additionally, Zonisade contains the rounded letter 'n' in the prefix, whereas Sudafed contains the upstroke letter 'd' in the prefix which may provide some differentiation. Furthermore, depending on how scripted, Sudafed contains the cross-stroke/downstroke letter 'f' or upstroke letter 'f' at the beginning of the suffix, which gives the names different shapes when scripted. Lastly, Zonisade contains the additional letter 'e' at the end of the suffix, which is not present in Sudafed which may provide additional differentiation of the name pair. Phonetically, the first syllables (Zaan vs. Soo), second syllables (i vs. duh), and third syllables (said vs fed) sound sufficiently different when spoken. Additionally, the brand name, Sudafed is a family name for an over the counter product line of cold and allergy products. These products are identified by the use of a modifier to differentiate the products. For example, Children's Sudafed Nasal Decongestant, Children's Sudafed PE, Sudafed Sinus Congestion 12 hours, Sudafed Sinus Congestion 24 hours, and Sudafed PE

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			Congestion. A prescription would need to include specific information to identify and differentiate between the products (e.g., strength and dosage form), which will provide additional differentiation between the name pair and this family of products. When all of the aforementioned mitigations are considered in totality, we find the risk of name confusion is mitigated to an acceptable level.
28.	Zamicet	60	This name pair has sufficient orthographic and phonetic differences. Orthographically, the suffixes (sade vs. cet) look sufficiently different when scripted. Phonetically, the rimes of the first syllables (/aan/ vs. /am/) and the third syllables (said/ vs. cet) sound different when spoken. Furthermore, the product characteristics may provide additional differentiation, if included: There is no direct overlap in strength (100 mg/5 mL [20 mg/mL]) versus 10 mg/325 mg per 15 mL) or frequency of administration (once or twice daily vs. every four to six hours as needed for pain). Additionally, Zamicet is a controlled substance (CII) and must include the product strength, directions for use and quantity to dispense on a

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			prescription.[e] These differences in the product characteristics can minimize the risk for confusion between products.
29.	Zanosar	60	This name pair has sufficient orthographic and phonetic differences.
30.	Zenzedi	60	This name pair has sufficient orthographic and phonetic differences.
31.	Zonatuss	60	This name pair has sufficient orthographic and phonetic differences.
32.	Clonidine	59	This name pair has sufficient orthographic and phonetic differences.
33.	Dotatate	59	This name pair has sufficient orthographic and phonetic differences.
34.	Genistein	59	This name pair has sufficient orthographic and phonetic differences.
35.	Laronidase	58	This name pair has sufficient orthographic and phonetic differences.
36.	Zonegran	58	This name pair has sufficient orthographic and phonetic differences. We note that Zonisade and Zonegran share the same active ingredient, same indication, same route of administration, same dose, and same frequency of administration. Therefore, if the products were confused or inadvertently substituted one for the other the patient would receive the same medication and identical dose of the intended drug,

[e] Code of Federal Regulations. 21CFR Part 1306.05(a)

No.	**Proposed name:** Zonisade **Established name:** zonisamide **Dosage form:** suspension **Strength(s):** 100 mg/5 mL (20 mg/mL) **Usual Dose:** Initial dose: 100 mg once daily; Titration: on day 14 may increase up to 100 mg every two weeks to (b) (4) 400 mg administered once or twice 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**
			thus minimizing the risk if the products were confused.
37.	Diazoxide	57	This name pair as sufficient orthographic and phonetic differences.
38.	Omniscan	57	This name pair has sufficient orthographic and phonetic differences.
39.	Prednisone	57	This name pair has sufficient orthographic and phonetic differences.
40.	Sebizon	57	This name pair has sufficient orthographic and phonetic differences.
41.	Zolpidem	57	This name pair has sufficient orthographic and phonetic differences.
42.	Benzonatate	56	This name pair has sufficient orthographic and phonetic differences.
43.	Tinaderm	56	This name pair has sufficient orthographic and phonetic differences.
44.	Zarontin	56	This name pair has sufficient orthographic and phonetic differences.
45.	Zeposia	56	This name pair has sufficient orthographic and phonetic differences.
46.	Ziprasidone	56	This name pair has sufficient orthographic and phonetic differences.
47.	Sublocade	55	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.	Zovia 1/35E-21	54
2.	Zovia 1/35E-28	54
3.	Zovia 1/50E-21	54
4.	Zovia 1/50E-28	54
5.	Benzonidazole	52
6.	Dow-Isoniazid	52

No.	Name	POCA Score (%)
7.	Isoniacinamide	52
8.	Monistat-Derm	52
9.	O-Anisaldehyde	52
10.	Niclosamide	50
11.	Fumasorb	48
12.	Nitazoxanide	48
13.	Sumycin	48

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.	Anisate	69	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	Dodecene	68	Product is not a drug. It is an alkene belonging to the family of acyclic alkenes, which functions as plasticizers, surfactant, resins, flavor, additive, and lubricant.
3.	Fonazine	68	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases.
4.	Zaditen	68	International product marketed and formerly marketed in multiple countries outside the US.
5.	Zimovane	67	International product marketed in Ireland and the United Kingdom.
6.	Banocide	66	International product marketed in India and formally marketed in United Kingdom.
7.	Donnaphen	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Ron Acid	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Amonafide	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Dimetane	64	Brand discontinued with no generic equivalents available. NDA 010799 withdrawn FR effective June 16, 2006.
11.	Lofensaid	64	International product formerly marketed in the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
12.	Minizide	64	Brand discontinued with no generic equivalents available. NDA 017986 withdrawn FR effective June 18, 2009.
13.	Sennoside B	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Dodatate	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Zanidip	63	International product marketed and formerly marketed in multiple countries outside the US.
16.	Aconitate	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	(b) (4) ***	62	Proposed proprietary name for ANDA 209547 found unacceptable by DMEPA (OSE# 2016-11676297). ANDA 209547 approved under the proprietary name, Malmorede.
18.	Cetazone	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Monistat 5	62	Brand discontinued with no generic equivalents available. NDA 018592 withdrawn FR effective June 4, 2004.
20.	Monocid	62	Brand discontinued with no generic equivalents available. NDA 050579 and ANDA 063295 withdrawn FR effective March 13, 2002 and November 12, 2002, respectively.
21.	(b) (4) ***	62	Proposed proprietary name for NDA 208969 found unacceptable by DMEPA (OSE# 2016-8072092 dated 07/26/2016). NDA 208969 received a complete response on 02/17/2017. NDA 208969 application is currently in Complete Response status.
22.	Nonivamide	62	Product is not a drug. It is an organic compound and a capsaicinoid. It is an amide of pelargonic acid and vanillyl amine. It is present in chili peppers, but is commonly manufactured synthetically.
23.	Simetone	62	Product is not a drug. It is a chemical compound that has a role as a herbicide, a xenobiotic and an environmental contaminant.
24.	Zefazone	62	Brand discontinued with no generic equivalents available. NDA 050637 withdrawn FR effective September 17, 2001.

No.	Name	POCA Score (%)	Failure preventions
25.	Zotepine	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Gentisate	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Domiphen	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Azosemide	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Butasone	60	Veterinary drug product.
30.	Butazone	60	Veterinary drug product.
31.	Cefonicid	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
32.	Disadine	60	International product formerly marketed in the United Kingdom and Ireland.
33.	Lotusate	60	Brand discontinued with no generic equivalents available. NDA 009410 withdrawn FR effective June 11, 1998.
34.	Soniazio	60	Name identified in RxNorm database, unable to identify product characteristics in commonly used databases.
35.	Xenaderm	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
36.	Zinc Iodide	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
37.	Dodicin	59	International product formally marketed in United Kingdom, Germany and Italy.
38.	Dynafed	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
39.	Monocete	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
40.	Zeniquin	59	Veterinary drug product.
41.	Anased	58	Veterinary drug product.
42.	Anise Oil	58	Product is not a drug. It is an essential oil.
43.	Digisan	58	International product marketed in Canada.
44.	Fungizone	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
45.	Junifen	58	International product marketed in Spain and formerly marketed in Belgium, United Kingdom, Portugal, Thailand, and Austria.

No.	Name	POCA Score (%)	Failure preventions
46.	Metazone	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Sinufed	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
48.	Sonahist	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
49.	Tanafed	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
50.	Vanacet	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
51.	Viskazide	58	Brand discontinued with no generic equivalents available. NDA 018872 withdrawn FR effective September 29, 1995.
52.	(b) (4) ***	58	The root name of the proposed proprietary name, (b) (4) *** for NDA 211210 found unacceptable by DMEPA (OSE# 2018-20453322 dated 03/27/2018). Proposed proprietary name, Qmiiz ODT*** was found conditionally acceptable under NDA 211210. NDA 211210 is currently pending.
53.	Zonulysin	58	International product formally marketed in United Kingdom and South Africa.
54.	Benzonate	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	Rinade-B.I.D.	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
56.	Ronidazole	57	Veterinary drug product.
57.	Aconitine	56	Drug product is not a drug. It is a chemical produced by the aconitum plant.
58.	Avobenzone	56	Product is not a standalone drug product. It is one of the active ingredients in sunscreen lotions
59.	Bumadizone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	Clonitrate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
61.	Flunisin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
62.	Fungisan	56	International product formerly marketed in Germany.

No.	Name	POCA Score (%)	Failure preventions
63.	Iodide Ion	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
64.	Iproniazid	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	Salzone	56	International product marketed in United Kingdom
66.	Sanisuds F-7125	56	Product is not a drug. It is a soap and hand sanitizer
67.	Sanisuds F-7250	56	Product is not a drug. It is a soap and hand sanitizer
68.	Santonin	56	Product is not a drug. It is a homeopathic preparation.
69.	Uniserts	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
70.	(b) (4) ***	56	Proposed proprietary name for BLA 761146 found unacceptable by DMEPA (OSE# 2019-36562853 dated March 4, 2020). BLA 761146 approved under proprietary name, QWO.
71.	Zomepirac	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	Zopiclone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Zymine D	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
74.	Inosine	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
75.	Monistat I.V.	55	Brand discontinued with no generic equivalents available. NDA 0018040 withdrawn FR effective July 25, 1997.
76.	Soni-Slo	55	International product formerly marketed in Ireland and the United Kingdom.
77.	Zingerone	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
78.	Anisindione	54	Brand discontinued with no generic equivalents available. NDA 010909 withdrawn FR effective December 7, 2007.
79.	Azdone	53	Brand discontinued with no generic equivalents available. ANDA 089420 withdrawn FR effective July 21, 2014.

No.	Name	POCA Score (%)	Failure preventions
80.	Cymevene	51	International product marketed and formerly marketed in multiple countries outside the US.

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

No.	Name	POCA Score (%)
1.	Donnapine	66
2.	Pennsaid	65
3.	Omnicide	64
4.	Uni-Sed	64
5.	Vanoxide	63
6.	Dezocine	62
7.	Farnesane	62
8.	Laniazid	62
9.	Oti-Sone	62
10.	Sine-Aid	62
11.	Donnazyme	61
12.	Valisone	61
13.	Benzoate	60
14.	Disotate	60
15.	Genasan	60
16.	Genesis	60
17.	Isobutane	60
18.	Linezolid	60
19.	Monafed DM	60
20.	Nazo-Mist	60
21.	Ozanimod	60
22.	Sani-Foam	60
23.	Senna Pod	60
24.	Teniposide	60
25.	Tineacide	60
26.	Vindesine	60
27.	Vanamide	60
28.	Dioxane	59
29.	Doksake	59

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

No.	Name	POCA Score (%)
30.	Econosone	59
31.	Isocetane	59
32.	Monensin	59
33.	Nerisone	59
34.	Slo-Niacin	59
35.	Synandone	59
36.	Acnecide	58
37.	(b) (4) ***	58
38.	Bionafem	58
39.	Bronkaid	58
40.	Condasin	58
41.	Dapsone	58
42.	Dolishale	58
43.	Etomidate	58
44.	Fenesin	58
45.	Isodettes	58
46.	Lomanate	58
47.	Lotrisone	58
48.	Med-I-San	58
49.	Menadione	58
50.	Motifene	58
51.	Naus-Aid	58
52.	N-Dodecane	58
53.	Noritate	58
54.	Normozide	58
55.	(b) (4) ***	58
56.	Phenazine	58
57.	Phenazine-35	58
58.	Phenazine 50	58
59.	Phen-Tuss Ad	58
60.	Pimozide	58
61.	Povidone	58
62.	Sanfed A	58
63.	Sansert	58
64.	Senna-Time	58
65.	Stintisone	58
66.	Swineaid	58
67.	Symadine	58
68.	Synercid	58
69.	Tedizolid	58
70.	Tizanidine	58
71.	Tonocard	58
72.	Uni Salve	58
73.	Uni-Case	58

No.	Name	POCA Score (%)
74.	Vendone	58
75.	Alenaze-D	57
76.	Amosene	57
77.	Benzoin	57
78.	Cinoxate	57
79.	Clinicide	57
80.	Desonate	57
81.	Genasec	57
82.	Isoditrate	57
83.	Modrasone	57
84.	Nasabid	57
85.	Noctesed	57
86.	R-Tannic-S A/D	57
87.	Soriatane	57
88.	Uni Serp	57
89.	Vesanoid	57
90.	Benzashave	56
91.	Benzashave 10	56
92.	Benzashave 5	56
93.	Benzene	56
94.	Bovadine	56
95.	Buminate	56
96.	Bunazosin	56
97.	Canineaid	56
98.	Cenolate	56
99.	Codafed	56
100.	Cortisone	56
101.	Cytisine	56
102.	Decazate	56
103.	Deltasone	56
104.	Demazin	56
105.	Dermazene	56
106.	Dexasone	56
107.	Didanosine	56
108.	Dimaphen	56
109.	Donatuss Dc	56
110.	Donepezil	56
111.	Donnagel	56
112.	Emeside	56
113.	Enovid-E	56
114.	Enovid-E 21	56
115.	Feminone	56
116.	Foam Safe	56
117.	Formestane	56

No.	Name	POCA Score (%)
118.	Funduscein	56
119.	Funduscein-25	56
120.	Fusidate	56
121.	Gonabreed	56
122.	Guanidine	56
123.	Guanosine	56
124.	Idoxene	56
125.	Konsyl-D	56
126.	Lanacane	56
127.	Lidosite	56
128.	Lindane	56
129.	Medicone	56
130.	Moditen	56
131.	Nitarsone	56
132.	Novafed	56
133.	Phenasep	56
134.	Phenesin	56
135.	Phenzene	56
136.	Phos-Aid	56
137.	Renacidin	56
138.	Sebutone	56
139.	Senna-Gen	56
140.	Sensi-Care	56
141.	Sensodyne	56
142.	Servisone	56
143.	Sincalide	56
144.	Solatene	56
145.	Somavert	56
146.	Stesolid	56
147.	Synvisc-One	56
148.	Tannate 12D S	56
149.	Tannic Acid	56
150.	Unifed	56
151.	Uni-Fed	56
152.	Vandazole	56
153.	Vanobid	56
154.	Venastat	56
155.	Xanthine	56
156.	Xeneisol	56
157.	Adzenys ER	55
158.	Amitone	55
159.	Antisedan	55
160.	Azatadine	55
161.	Azintamide	55

No.	Name	POCA Score (%)
162.	Azo-Gesic	55
163.	Bemisiose	55
164.	Cinolone	55
165.	Deblitane	55
166.	(b) (4) ***	55
167.	Flumezide	55
168.	Lidozen	55
169.	Lomitapide	55
170.	Minidiab	55
171.	Monoolein	55
172.	Normison	55
173.	Phanasin	55
174.	Pseudofed	55
175.	Razoxane	55
176.	Ridafed	55
177.	Ridifed	55
178.	Sani Guard	55
179.	Sani-Supp	55
180.	Sedivet	55
181.	Sinodec	55
182.	Somnite	55
183.	Vazobid	55

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/s/

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