CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

220711Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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:	April 22, 2026
Application Type and Number:	NDA 220711
Product Name, Dosage Form, and Strength:	Beqalzi (sonrotoclax) tablets, 1 mg, 5 mg, 20 mg, and 80 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	BeOne Medicines USA, Inc. (BeOne)
PNR ID #:	2026-1044727137
DMEPA 2 Safety Evaluator:	Jody Kundreskas, PharmD
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Beqalzi, which was found unacceptable under IND 161045 and NDA 220711 on December 18, 2025.[a] The proposed proprietary name, Beqalzi, was found to be vulnerable to medication errors due to confusion with another product, (b) (4)***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Beqalzi, was dependent upon which underlying application was approved first.

We note that the goal date for NDA 220711 is May 26, 2026, whereas the underlying application for (b) (4)*** remains in IND status. Therefore, if the proposed proprietary name, Beqalzi, is granted approval under NDA 220711 on or before May 26, 2026, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***.

Thus, BeOne resubmitted their preferred proposed proprietary name, Beqalzi, for review on March 25, 2026 under NDA 220711.[b]

2 DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Beqalzi, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, we searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 31, 2026 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Finally, we evaluated the status of the underlying application of the conflicting name, (b) (4)***, and determined that if NDA 220711 for Beqalzi is approved on or before May 26, 2026, this application approval will precede approval of the application with the conflicting proposed name, (b) (4)***, given the underlying application for (b) (4)*** remains in IND status.

Based upon our safety assessment of the proposed proprietary name, Beqalzi, the application goal date for NDA 220711, and the status of the underlying application for (b) (4)***, we find Beqalzi conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S DETERMINATION

On April 22, 2026, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

---

[a] Neshiewat, J. Proprietary Name Review for Beqalzi (IND 161045 and NDA 220711). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2025 DEC 18. PNR ID No. 2025-1044726551 and 2025-1044726736.

[b] Request for Proprietary Name Review – Beqalzi; Proprietary Name Withdrawal Request – (b) (4)*** (NDA 220711). Pennington (NJ): BeOne Medicines USA, Inc.; 2026 MAR 25. Available from: \\CDSESUB1\EVSPROD\nda220711\0032\m1\us\m1-2-cover-letter.pdf.

3 CONCLUSION

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

3.1 COMMENTS TO BEONE MEDICINES USA, INC.

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

If any of the proposed product characteristics as stated in your submission, received on March 25, 2026, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCE

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

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JODY K KUNDRESKAS
04/22/2026 07:05:49 AM

NICOLE F IVERSON
04/22/2026 07:08:44 AM

HINA S MEHTA
04/22/2026 12:25:55 PM

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:	December 18, 2025
Application Type and Number:	IND 161045; NDA 220711
Product Name, Dosage Form, and Strength:	Beqalzi (sonrotoclax) tablets, 1 mg, 5 mg, 20 mg, 80 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	BeOne Medicines USA, Inc. (BeOne Medicines)
PNR ID #:	2025-1044726551 and 2025-1044726736
DMEPA 2 Safety Evaluator:	Julie Neshiewat, PharmD, MS, BCPS, CPH
DMEPA 2 Team Leader:	Nicole Iverson, PharmD, BCPS
DMEPA 2 Associate Director for Nomenclature and Labeling:	Hina Mehta, PharmD

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Beqalzi, 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. BeOne Medicines submitted an external name study, conducted by (b) (4),[a] for this proposed proprietary name.

1.1 REGULATORY HISTORY

BeOne Medicines submitted the proposed proprietary name, Beqalzi, for review on June 24, 2025 under IND 161045 and September 26, 2025 under NDA 220711.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 24, 2025[b] and the prescribing information received on September 26, 2025.[c]

Table 1. Relevant Product Information for Beqalzi	
Intended Pronunciation:	bee kahl' zee
Active ingredient:	sonrotoclax
Indication:	treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) (b) (4) (b) (4)
Dosage Form:	tablets
Strength:	1 mg, 5 mg, 20 mg, 80 mg
Route of Administration:	oral

[a] Proprietary Name Safety Summary for Beqalzi. (b) (4); 2025 JUN 24. Available from: \\CDSESUB1\EVSPROD\ind161045\0057\m1\us\m1-18-proprietary-names.pdf.

[b] Proprietary Name Beqalzi IND 161045. Pennington (NJ): BeOne Medicines USA, Inc.; 2025 JUN 24. Available from: \\CDSESUB1\EVSPROD\ind161045\0057\m1\us\m1-18-proprietary-names.pdf.

[c] Proposed prescribing information for Beqalzi. Pennington (NJ): BeOne Medicines USA, Inc.; 2025 SEP 26. Available from: \\CDSESUB1\EVSPROD\nda220711\0001\m1\us\m1-14-1-3-draft-labeling-pi.pdf.

Table 1. Relevant Product Information for Beqalzi	
Dose and Frequency:	Recommended Dosage for Mantle Cell Lymphoma (b) (4) <u>Missed Dose</u> (b) (4) within 8 hours of the time it is usually taken, instruct the patient to take the missed dose as soon as possible with a meal and resume the normal daily dosing schedule. (b) (4) by more than 8 hours, instruct the patient to not take the missed dose and resume the usual dosing schedule the next day. If the patient vomits following a dose, instruct the patient to not take an additional dose that day and resume the usual dosing schedule the next day. (b) (4) <u>Dose Ramp-Up Schedule</u> Administer TRADENAME orally once daily, according to the (b) (4) (b) (4) ramp-up dosing schedule as shown in Table 1. The Starter Pack provides the first 4 weeks of TRADENAME according to the ramp-up schedule *[see How Supplied/Storage and Handling (16)]*. **Table 1: Dosing Schedule for 4-Week Ramp-Up Phase** **Week Number** / **Days** / **Daily Dose** / **Number of Tablets of Each Strength** **Week 1** / Days 1 to 3 / 1 mg / (1×) 1 mg Days 4 to 7 / 2 mg / (2×) 1 mg **Week 2** / Days 1 to 3 / 5 mg / (1×) 5 mg Days 4 to 7 / 10 mg / (2×) 5 mg **Week 3** / Days 1 to 3 / 20 mg / (1×) 20 mg Days 4 to 7 / 40 mg / (2×) 20 mg **Week 4** / Days 1 to 3 / 80 mg / (1×) 80 mg Days 4 to 7 / 160 mg / (2×) 80 mg

Table 1. Relevant Product Information for Beqalzi	
	(b) (4) Target Dose Week 5 and Beyond After completion of the 4-week ramp-up phase, the recommended dosage of TRADENAME is 320 mg (4 (b) (4) 80 mg tablets) taken orally once daily until disease progression or unacceptable toxicity. Dosage Modifications for Adverse Reactions (b) (4)

Table 1. Relevant Product Information for Beqalzi	
	(b) (4)

Table 1. Relevant Product Information for Beqalzi

(b) (4)

Table 5: Dose to Restart TRADENAME After a Dose Interruption Greater than 7 Days

Dose at Time of Interruption (mg)	Highest Restart Dose (mg)[a]
1 mg	1 mg
2 mg	1 mg
5 mg	2 mg
10 mg	5 mg
20 mg	10 mg
40 mg	20 mg
80 mg	40 mg
160 mg	80 mg
320 mg	160 mg

[a] The physician may restart at a lower dose than noted above.

Table 6: TRADENAME Dose with Moderate CYP3A Inhibitor (b) (4)

Original Sonrotoclax Dose (mg)	Sonrotoclax Dose When Administered with a CYP3A Moderate Inhibitor
1 mg	(b) (4) avoid moderate CYP3A inhibitor
2 mg	avoid moderate CYP3A inhibitor
5 mg	1 mg
10 mg	2 mg
20 mg	5 mg
40 mg	10 mg
80 mg	20 mg
160 mg	40 mg
320 mg	80 mg

Dosage Modifications for Drug Interactions

Strong or Moderate CYP3A Inhibitors

Strong CYP3A inhibitors are contraindicated (b) (4) at initiation and during ramp-up of TRADENAME. For dose adjustments, see (b) (4)

(b) (4)

Table 1. Relevant Product Information for Beqalzi

Table 7: Management of Potential TRADENAME Interactions with CYP3A Inhibitors

Coadministered Drug	During Initiation and Ramp-Up Phase	Target Daily Dose (after ramp-up phase)
Strong CYP3A inhibitors	Contraindicated	Reduce TRADENAME dose to 40 mg.
Moderate CYP3A inhibitors[a]	Avoid concomitant use of moderate CYP3A inhibitors at 1 mg and 2 mg dose of sonrotoclax. Reduce all other doses of sonrotoclax by at least 4-fold (see Table 6).	Reduce TRADENAME dose to 80 mg.

[a] (b) (4)
Consider alternative medicinal products or reduce the sonrotoclax dose as described in Table 6.

Resume the TRADENAME dosage that was used prior to treatment with a strong or moderate CYP3A inhibitor at least (b) (4) days after discontinuation of the inhibitor (b) (4).

(b) (4)

Table 1. Relevant Product Information for Beqalzi	
How Supplied:	(b) (4)
Storage:	Store at 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C and 30°C (59°F and 86°F) [see USP controlled room temperature].

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

BeOne Medicines did not provide a derivation or intended meaning for the proposed proprietary name, Beqalzi, in their submission.

The proposed proprietary name, Beqalzi, incorporates the letter string "Be", which is a part of the Sponsor's name, BeOne Medicines. Our Guidance for Industry Best Practices in Developing Proprietary Names for Human Prescription Drug Products recommends sponsors avoid proprietary names that incorporate the sponsor's name, or some part of the sponsor's name,

[d] USAN stem search conducted on July 31, 2025.

across multiple products (e.g., "ABCName1," "ABCName2," "ABCName3").[e] This practice can result in creating multiple similar proprietary names, which might increase the risk of confusion among the products. The practice can be problematic when products are stored alphabetically in distributor or pharmacy locations or when products are ordered from alphabetized lists. We note that the letter string "Be" is present in existing drug nomenclature across multiple sponsors (e.g., Belrapzo, Belsomra, Bendeka). We acknowledge that BeOne Medicines currently does not market any products in the US that incorporate all or part of the sponsor's name at this time. Because this is the first instance where BeOne Medicines proposed a proprietary name containing the letter string "Be", we do not object to the inclusion of "Be" in the proposed name.

Beqalzi does not contain any other components that can contribute to medication errors.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Hematologic Malignancies 2 (DHM 2) did not forward any comments or concerns relating to Beqalzi at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty practitioners participated in FDA's prescription simulation studies for Beqalzi. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[f] identified 52 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

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

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	50

[e] Guidance for Industry: Best Practices in Developing Proprietary Names for Human Prescription Drug Products. 2020. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-developing-proprietary-names-human-prescription-drug-products-guidance-industry.

[f] POCA search conducted on July 31, 2025 in version 5.13.7.

Low similarity name pair: combined match percentage score ≤54%	6

2.2.7 SAFETY ANALYSIS OF NAMES IDENTIFIED

We determined 56 of the 57 names will not pose a risk for confusion with Beqalzi as described in Appendices C through H. However, the proposed proprietary name could be confused with (b) (4) ***. The rationale for the risk of confusion is described below.

<u>Beqalzi vs. Reqelja***</u>

The proposed proprietary name, Beqalzi, may be confused with another pending proposed proprietary name that is also under review, (b) (4) *** (b) (4), due to orthographic similarities and overlapping product characteristics. (b) (4) *** is proposed for (b) (4).

Orthographically, Beqalzi and (b) (4) *** (b) (4) and share (b) (4) (b) (4) giving the names similar shapes when scripted. The prefixes ('Be' vs. (b) (4)) and infixes ('qal' vs. (b) (4)) may appear similar when scripted. Furthermore, the suffix of the name pair may appear similar when scripted (b) (4) (b) (4). We acknowledge that Beqalzi has a dotted letter 'i' in the last position whereas (b) (4). However, given the orthographic similarity of the rest of the name, this difference may not be sufficient to mitigate the risk of confusion.

In addition to the orthographic similarities, Beqalzi and (b) (4) *** share overlapping product characteristics, which can further increase the potential for wrong drug errors. (b) (4) (b) (4) (b) (4). We acknowledge the dosage forms are different (tablets vs. (b) (4) (b) (4).

We acknowledge the products differ in frequency of administration (once daily vs. (b) (4)). However, we are concerned that this difference may not prevent confusion between this name pair given the orthographic similarities of the names. We are aware of postmarketing reports of errors involving confusion between similarly named drug products, even when frequency of administration differ. For example, name confusion has been reported between Prenexa (prenatal vitamins) and Ranexa (ranolazine) despite their difference in frequency of administration (once daily vs. twice daily). [g]

We acknowledge that the products have different indications (proposed for treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have previously been treated with anti-CD20 based therapy and a Bruton's tyrosine kinase (BTK) inhibitor vs. (b) (4). However, we are concerned that this difference in indication may not prevent confusion between this name pair,

[g] Institute for Safe Medication Practices. Safety briefs: Ranexa and Prenexa too similar. ISMP Med Saf Alert Community/Ambulatory Care. 2012;11(3):1-4.

given the orthographic similarities and overlapping product characteristics. Despite widespread recommendations, only a small percentage of medications ordered include the indication.

We recognize that our conclusion differs from that of the [redacted] external name study submitted in support of the proposed proprietary name. However, the pending proprietary name is also under review and thus was not identified by the [redacted] external name study.

Therefore, based on the totality of the information above, we find the proposed proprietary name, Beqalzi, vulnerable to medication errors due to name confusion with [redacted]***.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On December 18, 2025, DMEPA 2 communicated our determination to the Division of Hematologic Malignancies 2 (DHM 2).

3 CONCLUSION

The proposed proprietary name, Beqalzi, is not acceptable from a safety perspective. The proposed proprietary name, Beqalzi, is vulnerable to name confusion with [redacted]***. Therefore, the decision to deny the proposed proprietary name will be communicated to BeOne Medicines via letter (See Section 3.1).

3.1 COMMENTS TO BEONE MEDICINES USA, INC.

We have completed our review of the proposed proprietary name, Beqalzi, and have concluded that this proprietary name is unacceptable for the following reasons.

Beqalzi vs. pending proprietary name

The proposed proprietary name, Beqalzi, could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, Beqalzi, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name Beqalzi, you will be requested to submit another name.

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

4 REFERENCES

1. United States Adopted Names (USAN) Stems

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

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

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

RxNorm

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

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

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

Purple Book

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

Division of Medication Errors Prevention and Analysis pending proprietary name requests

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

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

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

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[h]

Table 3. Prescreening Checklist for Proposed Proprietary Name
Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.

Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
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.

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

Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

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

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

Using the criteria outlined in the check list (Tables 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category that cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[i]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review. Additionally, when applicable, at the same time DMEPA requests concurrence/non-

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

concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

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

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

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

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

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).			
Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

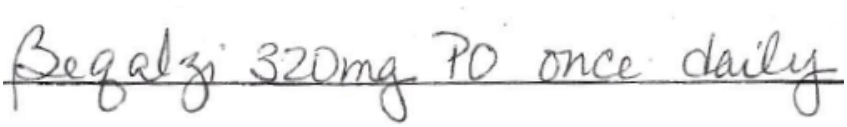
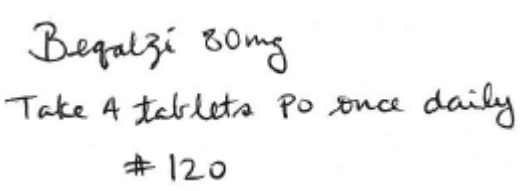
<table>
<tr><th colspan="3">Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is ≥55% to ≤69%).</th></tr>
<tr><td>Step 1</td><td colspan="2">Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.
For single strength products, also consider circumstances where the strength may not be expressed.
For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.
To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:
• Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa.
• Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.
• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td>Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.</td></tr>
<tr><td></td><td>Orthographic Checklist (Y/N to each question)
• Do the names begin with different first letters?
• Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.
• Are the lengths of the names dissimilar* when scripted?
*FDA considers the length of names different if the names differ by two or more letters.
• Considering variations in scripting of some letters (such as z and f), is there a different number or</td><td>Phonetic Checklist (Y/N to each question)
• Do the names have different number of syllables?
• Do the names have different syllabic stresses?
• Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤54%).**
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Beqalzi Study (Conducted on 7/7/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Inpatient:  	Beqalzi 80 mg Take 4 tablets by mouth once daily Dispense 120
Outpatient:  	
Computerized Prescription Order Entry (CPOE) Study Sample (displayed as sans-serif, 12-point, bold font)	
Beqalzi	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Beqalzi People Received Study: 161 People Responded: 80					
Total	22	19	18	21	80
INTERPRETATION	INPATIENT WRITTEN	OUTPATIENT WRITTEN	VERBAL	CPOE	TOTAL
BECALSI	0	0	1	0	1
BECALSY	0	0	1	0	1
BECALZI	0	0	3	0	3
BECALZY	0	0	4	0	4
BEGALZI	1	1	0	0	2
BEKALZE	0	0	1	0	1
BEKALZY	0	0	2	0	2
BENGALZI	0	1	0	0	1
BEQALZI	21	17	0	21	59
BICALZY	0	0	2	0	2
BIQELSI	0	0	1	0	1
ECALSY	0	0	1	0	1

ECALZY	0	0	1	0	1
EKALZI	0	0	1	0	1

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

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strengths: 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Beqalzi	100	This name is the subject of this review.

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

No.	Name	POCA Score (%)
1.	Bucalsep	59
2.	Betasal	58

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: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	
1.	Betalin 12	68	Orthographically, Beqalzi contains the down stroke letter ‘q’ in the third position while Betalin 12 contains the cross-stroke letter ‘t’ in the same position. In addition, the suffix of Beqalzi contains the optional downstroke letter ‘z’ followed by the dotted letter ‘i’ while the suffix of Betalin 12 contains the dotted letter ‘i’ followed

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	
			by the rounded letter 'n'. Furthermore, Betalin is available with the modifiers "12" or "S", which differentiates the name pair when the modifier is written. This name pair has sufficient phonetic differences. The products differ in dosage form (tablets vs. injection) and route of administration (oral vs. intramuscular or subcutaneous), which may provide additional differentiation. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Byqlovi	66	Orthographically, Byqlovi contains the down stroke letter 'y' in the second position, while Beqalzi contains the rounded letter 'e' in the same position. In addition, Beqalzi contains the letter string 'al' following the downstroke letter 'q' whereas Byqlovi contains the letter string 'lo' following the downstroke letter 'q'. Phonetically, the ending of the second syllable ('kahl' vs. 'kloe') and the beginning of the third syllable ('zee' vs. 'vee') sound different when spoken. The products differ in strength (1 mg, 5 mg, 20 mg, and 80 mg vs. 0.05%) and a

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	
			strength or dose would need to be included on a prescription for Beqalzi. Additionally, there is no overlap in dosage form (tablets vs. ophthalmic suspension), and route of administration (oral vs. ophthalmic) which may provide additional differentiation. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
3.	Balziva	63	This name pair has sufficient orthographic and phonetic differences.
4.	Balziva-21	63	This name pair has sufficient orthographic and phonetic differences.
5.	Balziva-28	63	This name pair has sufficient orthographic and phonetic differences.
6.	Betalin S	62	Orthographically, Beqalzi contains the down stroke letter ‘q’ in the third position while Betalin S contains the cross-stroke letter ‘t’ in the same position. In addition, the suffix of Beqalzi contains the optional downstroke letter ‘z’ followed by the dotted letter ‘i’ while the suffix of Betalin S contains the dotted letter ‘i’ followed by the rounded letter ‘n’. Furthermore, Betalin is available with the modifiers “S” or “12”, which differentiates the name pair when the modifier is written. This name pair has sufficient phonetic differences.

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	
			The products differ in dosage form (tablets vs. injection) and route of administration (oral vs. intramuscular or intravenous), which may provide additional differentiation. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
7.	Beta-Val	60	This name pair has sufficient orthographic and phonetic differences.
8.	Kisqali	58	Orthographically, the name pair begin with different first letters 'B' vs. 'K'. Beqalzi contains the rounded letter 'e' in the prefix while Kisqali contains the dotted letter 'i' followed by the rounded letter 's' in the prefix, which provides some orthographic difference. In addition, Beqalzi contains the optional downstroke letter 'z' in the suffix, while Kisqali contains the upstroke letter 'l' in the same position. Phonetically, the first syllable ('bee' vs. 'kis') and the beginning of the third syllable ('zee' vs. 'lee') sound different when spoken. Thus, in this specific case, the risk of name confusion between the name pair is minimized.
9.	(b) (4) ***	58	(b) (4)

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	(b) (4)
10.	(b) (4) ***	57	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Beqalzi Pronunciation: bee kahl' zee Established name: sonrotoclax Dosage form: tablets Strength(s): 1 mg, 5 mg, 20 mg, 80 mg Dosage: 1 mg, 2 mg, 5 mg, 10 mg, 20 mg, 40 mg, 80 mg, or 160 mg once daily	POCA Score (%)	
11.	Beldin	56	This name pair has sufficient orthographic and phonetic differences.
12.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
13.	Erelzi	56	Orthographically, the names begin with different letters (B vs. E). Beqalzi contains the downstroke letter 'q' in the third position whereas Erelzi contains the rounded letter 'e' in the same position. Phonetically, the beginning of the second syllable ('kahl' vs. 'rel') sound different when spoken. The products differ in dosage form (tablets vs. injection and for injection), route of administration (oral vs. subcutaneous), and frequency of administration (once daily vs. once weekly). Thus, in this specific case, the risk of name confusion between the name pair is minimized.
14.	Galzin	56	This name pair has sufficient orthographic and phonetic differences.
15.	Livdelzi	56	This name pair has sufficient orthographic and phonetic differences.
16.	Bebulin	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.	Equaline	50
2.	Bextra	48
3.	Rexulti	46
4.	Bendeka	41
5.	Benoquin	41
6.	Onglyza	36

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	68	Proposed proprietary name for (b) (4) found to be acceptable (OSE # (b) (4)). Name withdrawn by the Sponsor. Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable for (b) (4) (b) (4); however, (b) (4) received a complete response (b) (4).
2.	(b) (4) ***	64	Proposed proprietary name for (b) (4) found to be unacceptable due to a conflict with a marketed product (OSE # (b) (4)). IND (b) (4) is pending and no new names have been submitted.
3.	Belviq	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	(b) (4) ***	61	Proposed proprietary name for (b) (4) withdrawn by the Applicant. Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable for (b) (4). Entire application withdrawn by the Sponsor on (b) (4).
5.	Beqvez	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Baclezene	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
7.	Baicalin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
8.	Betaloc	58	International product in multiple countries including Canada, excluding the United States.
9.	Betulin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
10.	(b) (4) ***	58	Proposed proprietary name for (b) (4) found to be acceptable (OSE # (b) (4)); however, the entire application was withdrawn by the Sponsor on (b) (4).
11.	Dical-D	57	International product in Chile and Hong Kong.
12.	Basaljel	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
13.	Batilol	56	Product is not a drug. It is a batyl alcohol.
14.	(b) (4) ***	56	Proposed proprietary name for ANDA (b) (4) found to be conditionally acceptable (OSE # (b) (4)); however, the entire application was withdrawn by the Applicant on (b) (4).
15.	Benziq Ls	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
16.	Bepadin	56	Brand discontinued with no generic equivalents available. NDA 019001 withdrawn pending FR effective August 17, 2005.
17.	Betaloc-Sa	56	Name was identified in RxNorm database; however, it is listed without a modifier as Betaloc. International product in multiple countries including Canada, excluding the United States.
18.	Bucalcide	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
19.	Benziq	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
20.	Betacilin	55	Veterinary product listed as Betacilin Clav and Betacilin Clav Drops.
21.	Boscalid	55	Product is not a drug. It is a fungicide used in agriculture.

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

No.	Name	POCA Score (%)
1.	Amabelz	62
2.	Desal Ii	62
3.	Viberzi	62
4.	Leqselvi	60
5.	Lybalvi	60
6.	Zenalb	58
7.	Imkeldi	57
8.	Atelvia	56
9.	Xeglyze	56
10.	Zenalpha	56

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

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JULIE V NESHIEWAT
12/18/2025 02:47:08 PM

NICOLE F IVERSON
12/18/2025 03:04:30 PM

HINA S MEHTA
12/19/2025 08:27:12 AM