CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

211964Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	March 29, 2021
Application Type and Number:	NDA 211964
Product Name and Strength:	Qelbree (viloxazine) extended-release capsules, 100 mg, 150 mg, and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Supernus Pharmaceuticals, Inc. (Supernus)
PNR ID #:	2021-1044723836
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Qelbree, which was found conditionally acceptable under NDA 211964 on October 26, 2020.[a] A Complete Response Letter (CRL) was issued by the Agency for NDA 211964 on November 6, 2020. On February 2, 2021, Supernus submitted a Class 1 Resubmission of the NDA in response to the CRL. A request for proprietary name review of Qelbree was included in the NDA resubmission. We note that all product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The March 2, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Qelbree.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Psychiatry (DP). At that time, we also requested additional information or concerns that could inform our review. On March 24, 2021, the Division of Psychiatry (DP) stated no additional concerns with the proposed proprietary name, Qelbree.

3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Qelbree, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

[a] Holmes, L. Proprietary Name Review for Qelbree (NDA 211964). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Oct 26. Panorama No.: 2020-42990962.

3.1 COMMENTS TO SUPERNUS PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on February 2, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCE

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

   USAN Stems List contains all the recognized USAN stems.

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/s/

LORETTA HOLMES
03/29/2021 01:48:14 PM

SEVAN H KOLEJIAN
03/29/2021 01:48:14 PM

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	October 26, 2020
Application Type and Number:	NDA 211964
Product Name and Strength:	Qelbree (viloxazine) extended-release capsules, 100 mg, 150 mg, and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Supernus Pharmaceuticals, Inc. (Supernus)
Panorama #:	2020-42990962
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA, BCPPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Qelbree***, which was found unacceptable under NDA 211964 on May 27, 2020.[a] The proposed proprietary name, Qelbree***, was found to be vulnerable to medication errors due to potential confusion with another product, (b) (4) *** for IND (b) (4), under review at the time. Therefore the ultimate acceptability of the proposed proprietary name, Qelbree***, was dependent upon which underlying application was approved first.

Supernus resubmitted the proposed proprietary name, Qelbree***, for review on September 23, 2020. We note that the goal date for Qelbree***, NDA 211964, is November 8, 2020, whereas the application for the conflicting name remains in IND status. (b) (4)

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The October 9, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Qelbree***.

Based upon our safety assessment of the proposed proprietary name, Qelbree***, the application goal date for NDA 211964, and the status of IND (b) (4) we find Qelbree*** conditionally acceptable.

2.2 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

In response to the OSE, October 15, 2020 e-mail, the Division of Psychiatry (DP) stated that the Division has no concern(s) with the proposed proprietary name, Qelbree.***

3 CONCLUSION

We conclude that the proposed name, Qelbree***, is acceptable.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

[a] Holmes, L. Proprietary Name Review for Qelbree*** (NDA 211964). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 May 27. Panorama No.: 2020-38138425.

3.1 COMMENTS TO SUPERNUS PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 23, 2020, are altered prior to approval of the marketing application, the 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. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

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

/s/

LORETTA HOLMES
10/26/2020 11:30:22 AM

SEVAN H KOLEJIAN
10/26/2020 12:07:10 PM

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)

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

Date of This Review:	May 27, 2020
Application Type and Number:	NDA 211964
Product Name and Strength:	Qelbree (viloxazine) extended-release capsules, 100 mg, 150 mg, and 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Supernus Pharmaceuticals, Inc. (Supernus)
Panorama #:	2020-38138425
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA
DMEPA Deputy Director:	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Qelbree, 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. Supernus submitted an external name study, conducted by [redacted] (b) (4) for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on February 28, 2020.

- Intended Pronunciation: Kel' bree
- Active Ingredient: viloxazine
- Indication of Use: Treatment of attention deficit/hyperactivity disorder (ADHD) in pediatric patients ages 6 to 17 years.
- Route of Administration: Oral
- Dosage Form: Extended-release capsules
- Strengths: 100 mg, 150 mg, and 200 mg
- Dose and Frequency:

  Pediatric Patients 6-11 Years

  The recommended dose for pediatric patients 6-11 years of age is 100 mg-400 mg orally once daily. Titrate 100mg/week [redacted] (b) (4)

  Adolescent Patients 12-17 Years

  The recommended dose for adolescent patients 12-17 years of age is 200-[redacted] (b) (4) mg orally once daily. Titrate 200 mg/week [redacted] (b) (4)
- How Supplied: 100-count, 90-count, 60-count, and 30-count bottles.
- Storage: Store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F). [redacted] (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

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

Supernus indicated in their submission that the proposed proprietary name, Qelbree***, is derived from a blank canvas. This proprietary name is comprised of a single word that contains the letters "lb" which is the abbreviation for the word "pound". Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the lack of prominence of this abbreviation makes is unlikely that the letters "lb" within the proposed proprietary name, Qelbree***, would be confused as "pound" and lead to confusion in this case. Additionally, we note that the name Qelbree*** does not contain any other 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, March 20, 2020 e-mail, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Qelbree at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety (90) practitioners participated in DMEPA's prescription studies for Qelbree. 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[b] identified 16 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA and (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

[a] USAN stem search conducted on March 12, 2020.

[b] POCA search conducted on March 6, 2020 in version 4.3.

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%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	14
Low similarity name pair: combined match percentage score ≤54%	3

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

We determined 18 of the 19 names will not pose a risk for confusion with Qelbree*** 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.

Qelbree* vs. (b) (4) *****

The proposed proprietary name, Qelbree***, may be confused with another pending proposed proprietary name that is also under review, (b) (4)

(b) (4)

[c] POCA search conducted on March 12, 2020 in version 4.3.

We acknowledge that our conclusion differs from that of the external name study conducted by (b) (4) which concluded the proposed proprietary name Qelbree*** is acceptable. However, (b) (4)*** is a pending proposed proprietary name and, thus, was not identified in the (b) (4) study. Therefore, based on the totality of information provided above, we find the proposed proprietary name, Qelbree***, vulnerable to medication errors due to name confusion with (b) (4)***.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Psychiatry (DP) via e-mail on May 22, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Psychiatry (DP) on May 27, 2020, they stated no additional concerns with the proposed proprietary name, Qelbree***.

3 CONCLUSION

The proposed proprietary name, Qelbree***, is not acceptable from a safety perspective. The proposed proprietary name, Qelbree***, is vulnerable to name confusion with a pending name (b) (4)***. Therefore, the decision to deny the name will be communicated to Supernus via letter (see Section 3.1).

If you have further questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO SUPERNUS PHARMACEUTICALS, INC.

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

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

[e] Institute for Safe Medication Practices. Safety briefs. ISMP Med Saf Alert. 2001;6(18):1.

The proposed proprietary name, Qelbree, 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, Qelbree, 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, Qelbree, you will be requested to submit another name.

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.

3. ***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).

4. ***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).

5. ***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

APPENDICES

Appendix A

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

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

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

***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)).

[f] National Coordinating Council for Medication Error Reporting and Prevention. http://www nccmerp.org/aboutMedErrors html. Last accessed 10/11/2007.

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[g]. 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.

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.

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

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	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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.

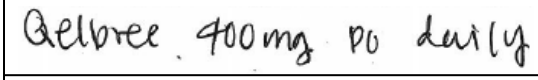
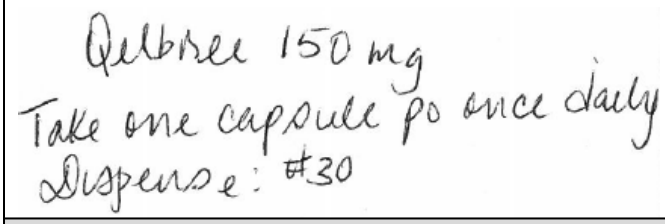
<table>
<tr><td></td><td colspan="2">• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="2">Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><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 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?</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 vowel reduction, assimilation, or deletion?
• Across a range of dialects, are the names consistently pronounced differently?</td></tr>
</table>

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. Qelbree Study (Conducted on March 13, 2020)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Qelbree 150 mg Take one capsule orally once daily Dispense #30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Qelbree	

FDA Prescription Simulation Responses (Aggregate Report)

	209 People Received Study	
	90 People Responded	
Study Name: Qelbree		

Total	**19**	**32**	**19**	**20**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
AELBREE	0	0	0	1	1
CALBRE	0	0	1	0	1
CALBRI	0	0	2	0	2
CELBREE	0	0	0	1	1
GELBREE	0	0	0	5	5
KALBRI	0	0	1	0	1
KELBREE	0	0	4	0	4
KELBRI	0	0	4	0	4

KELBRY	0	0	4	0	4	
KELGRY	0	0	1	0	1	
KELVARY	0	0	1	0	1	
KELVRY	0	0	1	0	1	
QELBREC	1	0	0	0	1	
QELBREE	16	32	0	13	61	
QELBREL	1	0	0	0	1	
QILBREE	1	0	0	0	1	

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

No.	**Proposed name:** Qelbree **Established name:** viloxazine **Dosage form:** Extended-release capsules **Strength(s):** 100 mg, 150 mg and 200 mg **Usual Dose:** Dosage range is 100 mg to (b) (4) mg orally 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.	Qelbree***	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.	Kelnor 1/50	62
2.	Teldrin	62
3.	Enbrel	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:** Qelbree **Established name:** viloxazine **Dosage form:** Extended-release capsules **Strength(s):** 100 mg, 150 mg and 200 mg **Usual Dose:** Dosage range is 100 mg to (b) (4) mg orally once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Celebrex	60	This name pair has sufficient orthographic and phonetic differences.
2.	Lybrel	59	This name pair has sufficient orthographic and phonetic differences.
3.	(b) (4) ***	56	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.	Qbrelis	53
2.	Breze	46
3.	Qvar	34

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.	Calabren	62	International product formerly marketed in the United Kingdom and Hong Kong
2.	Kelnor	62	This is the root name for Kelnor 1/35 and Kelnor 1/50. The root name Kelnor does not exist without one of these modifiers. The full name of the product would have to be specified on a prescription which would further help to mitigate potential confusion.
3.	Tildren	60	Veterinary product.

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

No.	Name	POCA Score (%)
1.	Colprep***	60
2.	Folbee	60
3.	Seebri	59
4.	(b) (4) ***	58
5.	Caltro	56

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

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/s/

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