CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215341Orig1s000

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 31, 2021
Application Type and Number:	NDA 215341
Product Name and Strength:	Kerendia (finerenone) tablets, 10 mg and 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bayer Healthcare Pharmaceuticals Inc. (Bayer)
Panorama or PNR ID #:	2021-1044723797
DMEPA Safety Evaluator:	Mariette Aidoo, PharmD, MPH
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Kerendia, which was found conditionally acceptable under IND 117847 on April 10, 2020.[a] Thus, Bayer submitted the name, Kerendia, under NDA 215341 for review on February 4, 2021. 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 Kerendia would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Cardiology and Nephrology (DCN) concurred with the findings of OPDP's assessment for Kerendia.

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 10, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Kerendia.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Cardiology and Nephrology (DCN). At that time we also requested additional information or concerns that could inform our review. On March 31, 2021, the Division of Cardiology and Nephrology (DCN) stated no additional concerns with the proposed proprietary name, Kerendia.

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, Kerendia, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO BAYER HEALTHCARE PHARMACEUTICALS INC.

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

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[a] Thomas, S. Proprietary Name Review for Kerendia (IND 117847). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 APR 10. Panorama No.: 2019-35160681.

If any of the proposed product characteristics as stated in your submission, received on February 4, 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.

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/

MARIETTE A AIDOO
04/05/2021 12:35:55 PM

HINA S MEHTA
04/05/2021 12:35:55 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:	April 10, 2020
Application Type and Number:	IND 117847
Product Name and Strength:	Kerendia (finerenone) tablets, 10 mg and 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bayer Healthcare Pharmaceuticals Inc. (Bayer)
Panorama #:	2019-35160681
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Bayer previously submitted the proposed proprietary name, (b) (4) *** on May 30, 2019. However, we found the name, (b) (4) *** unacceptable (b) (4) (b) (4)

Thus, Bayer submitted the name, Kerendia, for review on October 17, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on October 17, 2019.

- Intended Pronunciation: *kur-end-ee-ah*
- Active Ingredient: finerenone
- Indication of Use: (b) (4) reduce the risk of (b) (4) cardiovascular (b) (4) and hospitalization for heart failure in patients with chronic kidney disease and type 2 diabetes mellitus
- Route of Administration: oral
- Dosage Form: tablets
- Strength: 10 mg and 20 mg
- Dose and Frequency: The target dose of finerenone is 20 mg orally once daily. Patients under a certain eGFR level (TBD) may be started at 10 mg orally once daily before increasing to the target dose (based on serum potassium level and renal function).
- How Supplied: The tablets are planned to be provided in a white high density polyethylene (HDPE) bottle with white (b) (4) screw caps.
- Storage: (b) (4) (b) (4) (b) (4).

[a]Thomas, S. Proprietary Name Review for (b) (4) (IND 117847). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 21. Panorama No. 2019-32058111.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Bayer did not provide a derivation or intended meaning for the proposed proprietary name, Kerendia, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, November 14, 2019 e-mail, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to Kerendia at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-nine practitioners participated in DMEPA's prescription studies for Kerendia. 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[c] identified 103 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] USAN stem search conducted on March 10, 2020.

[c] POCA search conducted on March 10, 2020 in version 4.3.

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**
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	94
Low similarity name pair: combined match percentage score ≤54%	7

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

Our analysis of the 103 names contained in Table 1 determined none of the names will pose a risk for confusion with Kerendia 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 Cardiovascular and Renal Products (DCRP) via e-mail on April 8, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on April 10, 2020, they stated no additional concerns with the proposed proprietary name, Kerendia.

3 CONCLUSION

The proposed proprietary name, Kerendia, is acceptable.

If you have any questions or need clarifications, please contact Wana Manitpisitkul, OSE project manager, at 240-402-4156.

3.1 COMMENTS TO BAYER HEALTHCARE PHARMACEUTICALS INC.

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

A request for proprietary name review for Kerendia should be submitted once your marketing application is submitted.

If any of the proposed product characteristics as stated in your submission, received on October 17, 2019, 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. [d]

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

***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[e]. 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.

[e] 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.

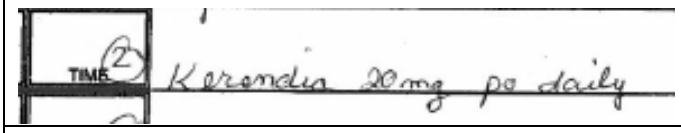
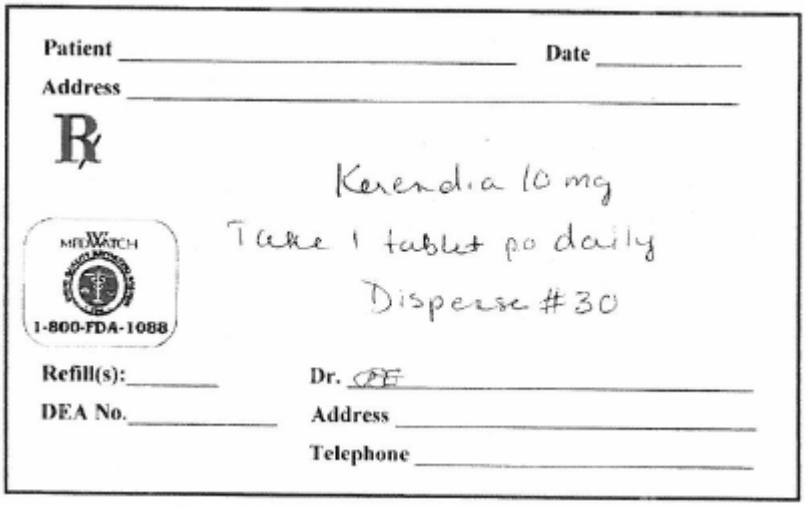
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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. Kerendia Study (Conducted on November 1, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Kerendia 10 mg Take one tablet by mouth daily Dispense thirty
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Kerendia	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Kerendia

As of Date 3/10/2020

215 People Received Study

79 People Responded

Study Name: Kerendia

Total	17	17	27	18	
INTERPRETATION	**CPOE**	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CARENDIA	0	0	5	0	5
CORENDIA	0	0	10	0	10
CORINDIA	0	0	2	0	2
CORINTHIA	0	0	1	0	1
CORRENDIA	0	0	1	0	1
CRENDIA	0	0	1	0	1
KARENDIA	0	0	4	0	4
KERANDIS	0	0	0	1	1
KERENDIA	17	17	1	6	41
KERONDIA	0	0	0	11	11
KORENDIA	0	0	1	0	1
KURENDIA	0	0	1	0	1

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

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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.	Cerenia	74	Veterinary product per DailyMed database.
2.	Kerendia	100	Proposed proprietary 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 (%)
3.	Renacidin	53

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:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
4.	Aredia	66	This name pair has sufficient orthographic and phonetic differences.
5.	Avandia	60	This name pair has sufficient orthographic and phonetic differences.
6.	Bendeka	56	This name pair has sufficient orthographic and phonetic differences.
7.	Cerinta	67	This name pair has sufficient orthographic and phonetic differences.
8.	Dyrenium	56	This name pair has sufficient orthographic and phonetic differences.
9.	Endari	52	This name pair has sufficient orthographic and phonetic differences.
10.	Erleada	51	This name pair has sufficient orthographic and phonetic differences.
11.	Exordia***	60	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
12.	Irenka	64	This name pair has sufficient orthographic and phonetic differences.
13.	Kaletra	55	This name pair has sufficient phonetic differences. The differing letters within the infixes of this name pair (ren vs. le) provide some orthographic differentiation. Additionally, the strengths of Kerendia (10 mg and 20 mg) do not directly overlap with Kaletra (80 mg lopinavir and 20 mg ritonavir per milliliter [oral solution], 200 mg lopinavir and 50 mg ritonavir [tablet], and 100 mg lopinavir and 25 mg ritonavir [tablet]) because there are two active ingredients in Kaletra. In addition, despite the overlap in dosage form and frequency of administration, Kaletra is available in multiple dosage forms (tablet and oral solution) and can be dosed once daily and twice daily. Therefore, the strength, dosage form, and frequency of administration may provide additional differentiation if included on a prescription and help minimize the risk of name confusion.
14.	Karbinal	55	Karbinal is a part of the product name Karbinal ER. The Kerendia and Karbinal ER name pair has sufficient orthographic and phonetic differences.
15.	Kariva	58	This name pair has sufficient orthographic and phonetic differences.
16.	Katerzia	60	This name pair has sufficient orthographic and phonetic differences.
17.	Kcentra	60	This name pair has sufficient phonetic differences.

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
			The extra letter "e" in Kerendia provides some orthographic differentiation between the name pair. Additionally, this name pair differs in strength (10 mg and 20 mg vs. actual potency for 500 unit vial ranges from 400-620 Factor IX units/vial, and the actual potency for 1000 unit vial ranges from 800-1240 Factor IX units/vial; when reconstituted, the final concentration of drug product in Factor IX units will be in a range from 20–31 units/mL), as well as dose (10 or 20 mg vs. weight-based and based on actual potency stated on the vial: 25 units of Factor IX/kg, 35 units of Factor IX/kg, or 50 units of Factor IX/kg with maximum dose of 2500 units to 5000 units of Factor IX). This name pair also differs in frequency of administration (once daily vs. now or once), route of administration (oral vs. intravenous), and dosage form (tablet vs. lyophilized powder for reconstitution); thus, these product characteristic differences provide additional differentiation if included on a prescription.
18.	Kedrab	55	This name pair has sufficient orthographic and phonetic differences.
19.	Kera Nail	68	This name pair has sufficient orthographic and phonetic differences.
20.	Kera-42	52	This name pair has sufficient orthographic and phonetic differences.
21.	Kerasal	55	This name pair has sufficient orthographic and phonetic differences.
22.	Kerosene	58	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
23.	Kerydin	66	This name pair has sufficient orthographic and phonetic differences. In addition, although this name pair may share numerical similarity in dose (1 tablet vs. 1 application), Kerendia and Kerydin are available in different strengths (10 mg and 20 mg vs. 5%). The products also differ in dosage form (tablet vs. topical solution) and route of administration (oral vs. topical); thus, these product characteristic differences provide additional differentiation if included on a prescription.
24.	Kesimpta***	57	This name pair has sufficient phonetic differences. The suffixes of this name pair provide orthographic differences, specifically with the downstroke p in Kesimpta*** not present in Kerendia. Although Kerendia and Kesimpta*** overlap in strength (20 mg) and dose (20 mg), the products differ in route of administration (oral vs. subcutaneous), dosage form (tablets vs. injection), and frequency of administration (once daily vs. administered at week 0, 1 and 2 or monthly at week 4); thus, these product characteristic differences provide additional differentiation if included on a prescription.
25.	Keytruda	57	This name pair has sufficient orthographic and phonetic differences.
26.	Klerist-D	56	This name pair has sufficient orthographic and phonetic differences.
27.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
28.	Krintafel	60	This name pair has sufficient orthographic and phonetic differences.
29.	Kyleena	58	This name pair has sufficient orthographic and phonetic differences.
30.	Migrend	56	This name pair has sufficient orthographic and phonetic differences.
31.	Mirena	57	This name pair has sufficient orthographic and phonetic differences.
32.	Orencia	66	This name pair has sufficient orthographic and phonetic differences.
33.	(b) (4) ***	61	This name pair has sufficient orthographic and phonetic differences.
34.	Prandin	62	This name pair has sufficient orthographic and phonetic differences.
35.	Rekynda***	60	This name pair has sufficient orthographic and phonetic differences. Of note, the proposed proprietary name was found unacceptable because it would misbrand the proposed product on February 23, 2017 under IND 064119 (Panorama #: 2017-12412628).
36.	Reno-Dip	56	This name pair has sufficient orthographic and phonetic differences.
37.	Renvela	56	This name pair has sufficient orthographic and phonetic differences.
38.	Saxenda	57	This name pair has sufficient orthographic and phonetic differences.
39.	Stendra	55	This name pair has sufficient orthographic and phonetic differences.
40.	Treanda	69	This name pair has sufficient phonetic differences. The prefixes (Ke vs. Tre) provide some orthographic differences between the name pair. Additionally, although the products share numerical similarity in strength (10 mg vs. 100 mg) and dose (10 mg

No.	**Proposed name:** Kerendia **Established name:** finerenone **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg or 20 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**
			vs. 100 mg/m^2), they differ in route of administration (oral vs. intravenous), dosage form (tablet vs. injection or for injection), and frequency of administration (once daily vs. administered on days 1 and 2 of a 28-day or 21-day cycle); thus, these product characteristic differences provide additional differentiation if included on a prescription.
41.	Trental	58	This name pair has sufficient orthographic and phonetic differences.
42.	Trokendi	66	Trokendi XR and Kerendia have sufficient orthographic and phonetic differences.

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
43.	Alkeran I.V.	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	Aprindine	58	International product marketed in Germany, Japan, Spain, and other countries per Micromedex database.
45.	Ceredase	60	Brand discontinued with no generic equivalents available. NDA 020057 withdrawn FR effective April 18, 2012.
46.	Defend Ii	68	Veterinary product per DailyMed database.

No.	Name	POCA Score (%)	Failure preventions
47.	Dendrid	53	Brand discontinued with no TE codes provided per Drugs@FDA database.
48.	(b) (4) ***	52	(b) (4)
49.	Eraldin	54	International product marketed in Australia, Argentina, and the United Kingdom per Micromedex database.
50.	(b) (4) ***	55	Proposed proprietary name found unacceptable on March 14, 2018 under ANDA 210612 (Panorama #: 2017-19632864 and 2017-19808344). ANDA 210612 approved under established names, estradiol and norethindrone acetate.
51.	Karidium	60	Karidium is an unapproved product deactivated over 20 years ago with no generic equivalents.
52.	Kemadrin	55	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
53.	Kronofed-A	60	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
54.	Meridia	66	Brand discontinued with no generic equivalents available per Drugs@FDA database. NDA 020632 withdrawn FR effective December 21, 2010.
55.	(b) (4) ***	64	(b) (4)
56.	Perestan	55	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
57.	Prandimet	60	Brand discontinued with no generic equivalents available per Drugs@FDA database. NDA 022386 withdrawn FR effective August 13, 2018.
58.	(b) (4) ***	68	(b) (4)

No.	Name	POCA Score (%)	Failure preventions
59.	Sarenin	60	Brand discontinued with no generic equivalents available per Drugs@FDA database. NDA 018009 withdrawn FR effective September 29, 1995.
60.	Serenace	60	International product marketed in many countries including the United Kingdom per Tox and Drug Product Lookup database.
61.	Serentil	65	Brand discontinued with no generic equivalents available per Drugs@FDA database. NDA 016774, NDA 016775, and NDA 016997 withdrawn FR effective March 26, 2018.
62.	Suprenza	57	Brand discontinued with no generic equivalents available per Micromedex Redbook database. NDA 202088 withdrawn FR effective July 21, 2017.
63.	Terfenadine	60	Brand discontinued with no generic equivalents available per Micromedex Redbook database.
64.	Trandide	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	Tripedia	66	Brand discontinued with no generic equivalents available per Micromedex Redbook database.

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 (%)
66.	Cardene	56
67.	Cardene Iv	59
68.	Carzenide	58
69.	Ceramide 6 Ii	58
70.	Cerianna***	57
71.	Ceron-Dm	56
72.	Clenia	58
73.	Convenia	55
74.	Copper Edta	58
75.	Coremino***	56
76.	Corphedra	56

[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 (%)
77.	Cortenema	55
78.	Credelio	57
79.	Daranide	58
80.	Degen Ii	56
81.	Ferndex	56
82.	Geranial	61
83.	Germa-Medica	56
84.	Hizentra	56
85.	Jeridin	58
86.	(b) (4) ***	61
87.	Paredrine	56
88.	Perdiem	55
89.	Peroxin A	55
90.	Peroxin A 10	55
91.	Predair	56
92.	Predenema	57
93.	Sertindole	56
94.	Teargen Ii	58
95.	(b) (4) ***	61
96.	Teramine Er	56
97.	Tetramed	55
98.	(b) (4) ***	56
99.	Trandate	65
100.	Tridrane	55
101.	Trumenba	55
102.	Verzenio	56
103.	(b) (4) ***	55

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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:	August 21, 2019
Application Type and Number:	IND 117847
Product Name and Strength:	(b) (4) (finerenone) Tablets, 10 mg and 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Bayer Healthcare Pharmaceuticals, Inc. (Bayer)
Panorama #:	2019-32058111
DMEPA Safety Evaluator:	Sarah Thomas, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

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08/22/2019 11:41:26 AM