CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

021164Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	March 21, 2023
Application Type and Number:	NDA 021164
Product Name and Strengths:	Exxua (gepirone) extended-release tablets, 18.2 mg, 36.3mg, 54.5 mg and 72.6 mg[a]
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Fabre-Kramer Pharmaceuticals, Inc. (Fabre-Kramer)
PNR ID #:	2022-1044724916
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
Acting DMEPA 1 Team Leader:	Madhuri R. Patel, PharmD
DMEPA 1 Director:	Mishale Mistry, PharmD, MPH

[a] Per the Office of Pharmaceutical Quality (OPQ), the strengths will be expressed based on free base gepirone (18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg) and not the gepirone HCl salt (20 mg, 40 mg, 60 mg, and 80 mg, respectively). According to OPQ, this was communicated to the Applicant. In the Applicant's Request for Proprietary Name Review document, the product strengths presented are based on the salt.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Exxua, 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. Fabre-Kramer did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Fabre-Kramer initially submitted the proposed proprietary name, Ariza***, for review in 2000 under IND 033626 and the name was found conditionally acceptable. The name was re-reviewed in 2001 under NDA 021164 and was found unacceptable due to orthographic and phonetic similarities, and shared product characteristics with the proprietary name, Arava.[b]

Subsequently, the proposed name Variza*** was submitted for review under NDA 021164. However, the name Variza*** was found unacceptable on April 30, 2004 due to orthographic similarities and shared product characteristics with the proprietary name Vaniqa and orthographic and phonetic similarities and shared product characteristics with the proprietary name Vidaza.[c]

Thus, Fabre-Kramer submitted the name, Travivo***, for review under NDA 021164. The name was found conditionally acceptable on November 14, 2007.[d] We note that the Agency issued a Not Approvable letter for the NDA on November 2, 2007.

On June 16, 2014, Fabre-Kramer submitted a Formal Dispute Resolution Request appealing the Not Approvable letter dated November 2, 2007. On March 16, 2016, the Office of New Drugs issued an Appeal Granted letter.

On April 8, 2019, the name, Travivo***, was submitted for review under IND 033626. However, the name was found unacceptable on October 1, 2019 due to orthographic similarities and shared product characteristics with the proprietary name, Tarceva.[e]

On January 19, 2021, Fabre-Kramer submitted the proposed proprietary name, Exxua, for review under IND 033626. The name was found conditionally acceptable on June 25, 2021.[f]

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[b] Diwa, D. Proprietary Name Review for Ariza (NDA 021164). Silver Spring (MD): FDA, CDER, OSE, DMETS (US); 2002 Jan 02. OSE No. 01-0164.

[c] Harper-Velazquez, T. Proprietary Name Review for Variza (NDA 021164). Silver Spring (MD): FDA, CDER, OSE, DMETS (US); 2004 Apr 30. OSE No. 04-0053.

[d] Taylor, K. Proprietary Name Label and Labeling Review for Travivo (NDA 021164). Silver Spring (MD): FDA, CDER, OSE, DMETS (US); 2007 Nov 14. OSE No. 2007-542.

[e] Holmes, L. Proprietary Name Review for Travivo (IND 033626). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Oct 1. Panorama No. 2019-30639998.

[f] Holmes, L. Proprietary Name Review for Exxua (NDA 021164). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Jun 25. PNR ID No. 2021-1044723766.

On December 23, 2022, Fabre-Kramer submitted a complete response to the Appeal Granted Letter (dated March 16, 2016) and concurrently submitted a request for proprietary name review of Exxua under NDA 021164, which is the subject of this review.

We note that the strengths have changed (from 20 mg, 40 mg, 60 mg, and 80 mg to 18.2 mg, 36.3mg, 54.5 mg and 72.6 mg, respectively) since our previous review of the name.[g]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on December 23, 2022.

- Intended Pronunciation: ex' zoo ah
- Active Ingredient: gepirone
- Indication of Use: treatment of major depressive disorder (MDD) in adults
- Route of Administration: oral
- Dosage Form: extended-release tablets
- Strengths: 18.2 mg, 36.3mg, 54.5 mg and 72.6 mg[h]
- Dose and Frequency:[i] The usual target dose is 54.5 mg to 72.6 mg (1 tablet) once daily. The recommended starting dose is 18.2 mg (1 tablet) administered orally once daily with food at approximately the same time each day. If the 18.2 mg initial dose is adequately tolerated, an increase to 36.3 mg (1 tablet) given once daily may begin as early as Day 4 of dosing. If the 36.3 mg dose is well tolerated and additional efficacy is desired, the dose may be increased to 54.5 mg (1 tablet) after one week and to 72.6 mg(1 tablet) after an additional week.

  Hepatic Impairment

  The recommended starting dose in patients with (b) (4) moderate hepatic impairment (Child-Pugh (b) (4) B) is 18.2 mg (1 tablet) once daily. (b) (4) . Exxua is contraindicated in patients with severe hepatic impairment (Child-Pugh C).

  Renal Impairment

  No dosage modification is required in patients with mild renal impairment (creatinine clearance ≥ 50 mL/min). The recommended starting dose in patients with moderate to

[g] Per the Office of Pharmaceutical Quality (OPQ), the strengths will be expressed based on free base gepirone (18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg) and not gepirone HCl salt (20 mg, 40 mg, 60 mg, and 80 mg, respectively). According to OPQ, this was communicated to the Applicant. In the Request for Proprietary Name Review document, the product strengths presented are based on the salt.

[h] Per Office of Pharmaceutical Quality (OPQ), the strengths will be expressed based on free base gepirone (18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg) and not gepirone HCl salt (20 mg, 40 mg, 60 mg, and 80 mg, respectively).

[i] We considered in our assessment the dose expressed based on free base gepirone, for consistency with the strength expression.

severe renal impairment (creatinine clearance <50 mL/min) is 18.2 mg (1 tablet) once daily. (b) (4).

- How Supplied: Bottles of 100
- Storage: Store at 25°C (77°F); excursions are permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from high humidity and moisture.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Exxua would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Exxua. The Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Exxua.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Fabre-Kramer indicated in their submission that the proposed proprietary name, Exxua, was derived from the "(b) (4)." This proprietary name is comprised of a single word that contains the medical abbreviation "EX", at the beginning of the name, which means "extra strength". We typically discourage the inclusion of medical abbreviations in proprietary names. However, "EX" is typically used as a modifier that is located after the product's root name (e.g., Drugname EX) and thus it is unlikely that "EX" would be confused as "extra strength" in the name in this case. However, we evaluated the potential risk of misinterpreting the proposed name, Exxua, as "EX [drug name Xua]" and did not identify any names of concern.[k] This name does not contain any other components (i.e., a modifier, route of administration, dosage form, etc.) that can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

On February 6, 2023, the Division of Psychiatry (DP) did not forward any comments or concerns relating to Exxua at the initial phase of the review.

[j] USAN stem search conducted on February 14, 2023.

[k] POCA search for "xua" conducted on February 17, 2023 in version 5.2.

2.2.4 FDA Name Simulation Studies

Eighty-five (85) practitioners participated in DMEPA's prescription studies for Exxua. One participant in the Computerized Physician Order Entry (CPOE) portion of the FDA Name Simulation Studies incorrectly selected the proprietary name, Exubera. However, we note that the participant entered an incorrect sequence of letters, "exu" instead of "exx" when searching for the study name. As a result, CPOE generated a pick list that did not contain Exxua as a choice. The participant proceeded to incorrectly select Exubera after 56 seconds of pausing. Thus, in this case, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study.

Exxua vs. Exubera

Exubera (insulin recombinant human) NDA 021868 is an inhaled insulin indicated for the treatment of adult patients with diabetes mellitus for the control of hyperglycemia. NDA 021868 was withdrawn FR effective 06/18/2009. Additionally, this product is discontinued per Red Book and no generic equivalents are available on the market. Based on the totality of consideration above, we determined that the risk for a medication error between this name pair is adequately minimized (see Appendix G).

The remaining 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[l] identified 31 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. Since our previous review, we note that the product strengths and doses have changed from 20 mg, 40 mg, 60 mg, and 80 mg (based on gepirone HCl salt) to 18.2 mg, 36.3 mg, 54.5 mg, and 72.6 mg, respectively (based on free base gepirone) and we considered these changes in our re-evaluation of the name. We agree with the findings from our previous review for the names evaluated previously. Therefore, we identified one name not previously analyzed. This name is included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Names Retrieved for Review Organized by Name Pair Similarity

[l] POCA search conducted on February 14, 2023 in version 5.2.

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%	1
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the two names contained in Table 1 determined the names will not pose a risk for confusion with Exxua as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On March 21, 2023, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Exxua, is conditionally acceptable.

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

3.1 COMMENTS TO FABRE-KRAMER PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on December 23, 2022, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

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. [m]

***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)).

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

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

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

each consisting of a combination of marketed and unapproved drug products, including the proposed name.

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.			
Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	**Y/N**	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	**Y/N**	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there	**Y/N**	Do the syllables have different phonologic processes, such

	a different number or placement of upstroke/downstroke letters present in the names?		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.

<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. Exxua Study (Conducted on February 14, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order: Exxua 72.6mg po once daily	Exxua 54.5 mg Take one tablet by mouth once daily Dispense 30
Outpatient Prescription: Exxua 54.5 mg Take one tablet po once daily Dispense #30	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Exxua	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Exxua					
257 People Received Study					
85 People Responded					
Total	24	21	21	19	
INTERPRETATION	INPATIENT	CPOE	VOICE	OUTPATIENT	TOTAL
A	0	0	1	0	1
ABZULA	0	0	1	0	1
ACZUA 54.5 MG	0	0	1	0	1
AXXUA	1	0	0	0	1
AXZUA	0	0	1	0	1
EPZULA	0	0	1	0	1
EXUA	0	0	1	0	1
EXUBERA	0	1	0	0	1
EXULA	0	0	3	0	3
EXXELA	1	0	0	0	1
EXXMA	1	0	0	0	1

EXXNA	1	0	0	0	1
EXXUA	20	20	0	19	59
EXZOOA	0	0	1	0	1
EXZUA	0	0	5	0	5
EXZULA	0	0	2	0	2
XSUA	0	0	1	0	1
XZUA	0	0	2	0	2
XZULA	0	0	1	0	1

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

No.	**Proposed name:** Exxua **Established name:** gepirone **Dosage form:** Extended-release tablets **Strengths:** 18.2 mg, 36.3mg, 54.5 mg and 72.6 mg **Usual Dose:** 18.2 mg, 36.3 mg, 54.5 mg, or 72.6 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.	Bexxar	70	Brand discontinued. BLA 125011 license revoked effective 03/10/2014.

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 — N/A

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose — N/A

Appendix F: Low Similarity Names (e.g., combined POCA score is ≤54%) — 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
1.	Exubera	57	NDA 021868 was withdrawn FR effective 06/18/2009. Additionally, this product is discontinued per Red Book and no generic equivalents are available on the market. (This name was also identified in our previous proprietary name review.)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion.[o] — N/A

[o] 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

APPEARS THIS WAY ON ORIGINAL

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LORETTA HOLMES
03/21/2023 04:03:36 PM

MADHURI R PATEL
03/21/2023 08:33:35 PM

MISHALE P MISTRY
03/22/2023 02:19:31 PM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Surveillance and Epidemiology

Date:	November 14, 2007
To:	Thomas Laughren, Director Division of Psychiatry Products
Thru:	Linda Kim-Jung, Team Leader, DMETS Denise Toyer, Deputy Director, DMETS Carol Holquist, Director, DMETS
From:	Kellie Taylor, Team Leader, DMETS
Subject:	Proprietary Name, Label, and Labeling Review for Travivo
Drug Name(s):	Travivo (Gepirone Hydrochloride Extended-release tablets)
Application Type/Number:	NDA 21-164
Applicant/sponsor:	(b) (4)/Fabre-Kramer Pharmaceuticals
OSE RCM #:	2007-542

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/s/

Kellie Taylor
11/14/2007 08:55:11 AM
DRUG SAFETY OFFICE REVIEWER

Denise Toyer
11/14/2007 11:55:35 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
11/14/2007 04:39:53 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE
DIVISION OF MEDICATION ERRORS AND TECHNICAL SUPPORT
OFFICE OF DRUG SAFETY
(DMETS; HFD-420)

DATE RECEIVED: Feb. 19, 2004 **DOCUMENT DATE:** Feb. 9, 2004	**DESIRED COMPLETION DATE:** April 19, 2004	**ODS CONSULT #:** 04-0053

TO: Russell Katz, M.D.
Director, Division of Neuropharmacological Drug Products
HFD-120

THROUGH: Paul David
Project Manager
HFD-120

PRODUCT NAME: **Variza™** (Gepirone Extended-Release Tablets) 20 mg, 40 mg, and 60 mg **NDA #**: 21-164	**SPONSOR:** Organon

SAFETY EVALUATOR: Tia M. Harper-Velazquez, Pharm.D.

RECOMMENDATIONS:

1. DMETS does not recommend the use of the proprietary name, Variza™.

2. DMETS recommends implementation of the label and labeling revisions outlined in Section III of this review to minimize potential errors with the use of this product.

3. DDMAC finds the proprietary name Variza™ acceptable from a promotional perspective.

Carol Holquist, R.Ph.
Director
Division of Medication Errors and Technical Support
Office of Drug Safety
Phone: (301) 827-3242 Fax: (301) 443-9664

Division of Medication Errors and Technical Support
Office of Drug Safety
HFD-420; Parklawn Rm. 6-34
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: March 31, 2004

NDA: 21-164

NAME OF DRUG: **Variza™**
(Gepirone Extended-Release Tablets)
20 mg, 40 mg, and 60 mg

NDA SPONSOR: Organon

*****NOTE: This review contains proprietary and confidential information that should not be released to the public. *****

(b) (4)

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/s/

Tia Harper-Velazquez
4/30/04 10:14:50 AM
DRUG SAFETY OFFICE REVIEWER

Alina Mahmud
4/30/04 10:18:11 AM
DRUG SAFETY OFFICE REVIEWER

Carol Holquist
4/30/04 02:28:22 PM
DRUG SAFETY OFFICE REVIEWER

CONSULTATION RESPONSE
Office of Post-Marketing Drug Risk Assessment
(OPDRA; HFD-400)

DATE RECEIVED: July 19, 2001	**DUE DATE:** December 30, 2001	**OPDRA CONSULT #:** 01-0164

TO: Russell Katz, M.D.
Director, Division of Neuropharmacological Drug Products
HFD-120

THROUGH: Paul David, Project Manager
HFD-120

PRODUCT NAME: Ariza (Gepirone HCl Extended-release Tablets) 20 mg, 40 mg, 60 mg and 80 mg

NDA#: 21-164

MANUFACTURER: (b) (4)

SPONSOR: Organon

SAFETY EVALUATOR: David Diwa, Pharm.D.

SUMMARY: In response to a consult from the Division of Neuropharmacological Drug Products (HFD-120), OPDRA conducted a re-evaluation of the proposed proprietary name "Ariza" to determine the potential for confusion with approved proprietary and generic names as well as pending names since the last review (00-0086).

OPDRA RECOMMENDATION: OPDRA does not recommend the use of the proprietary name, Ariza based on information currently available.

Jerry Phillips, R.Ph.
Associate Director for Medication Error Prevention
Office of Post-Marketing Drug Risk Assessment
Phone: (301) 827-3242
Fax: (301) 480-8173

Martin Himmel, M.D.
Deputy Director
Office of Post-Marketing Drug Risk Assessment
Center for Drug Evaluation and Research
Food and Drug Administration

Office of Post-Marketing Drug Risk Assessment
HFD-400; Rm. 15B32
Center for Drug Evaluation and Research

PROPRIETARY NAME REVIEW

DATE OF REVIEW: **December 14, 2001**

IND NUMBER: **21-164**

NAME OF DRUG: **Ariza (Gepirone HCl Extended-release Tablets)**
20 mg, 40 mg, 60 mg and 80 mg

NDA HOLDER: **Organon**

(b) (4)

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/s/

David Diwa
12/31/01 11:15:13 AM
PHARMACIST

Jerry Phillips
12/31/01 11:21:07 AM
DIRECTOR

Martin Himmel
1/2/02 07:52:03 AM
MEDICAL OFFICER