CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215151Orig1s000

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 public*****

Date of This Review:	July 31, 2023
Application Type and Number:	NDA 215151
Product Name and Strength:	Voquezna (vonoprazan) tablets, 10 mg and 20 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Phathom Pharmaceuticals, Inc. (Phathom)
PNR ID #:	2023-1044725147
DMEPA 1 Safety Evaluator:	Sherly Abraham, R.Ph.
DMEPA 1 Team Leader:	Idalia E. Rychlik, Pharm.D.
DMEPA 1 Director (Acting):	Irene Z. Chan, Pharm.D.

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

We found the name, Voquezna, Voquezna Dual Pak and Voquezna Triple Pak acceptable under NDA 215151, NDA 215153 and NDA 215152 respectively on April 26, 2022[a]; however, the application for Voquezna received a complete response (CR) due to product quality issues.[b] The application for Voquezna Dual Pak (NDA 215153) and Voquezna Triple Pak (NDA215152) were approved on May 3, 2022.[c]

Thus, Phathom resubmitted the proposed proprietary name, Voquezna on May 19, 2023, under NDA 215151 for our review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission and prescribing information received on May 19, 2023.

- Intended Pronunciation: voe kwez' nah
- Active Ingredient: vonoprazan
- Indication of Use:

  Voquenza is indicated:

  - for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
  - to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.

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[a] Myers, D. Proprietary Name Review for Voquezna, Voquezna Dual Pak and Voquezna Triple Pak NDA 215151, NDA 215153, and NDA 215152. Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 APR 26. PNR ID Nos. 2022-1044724493, 2022-1044724481, and 2022-1044724480.

[b] Dewey, M. FDA Communication: Complete Response letter for Voquezna (NDA 215151). Silver Spring (MD): FDA, CDER, OND, DG (US); 2023 FEB 7. Available at: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af806b07ab

[c] Voquezna Dual Pak and Voquezna Tripak will be marketed on November 30, 2023. Available at: https://dqcp.fda.gov/dqcp/f?p=1105:721:300811018828791::NO::P721_RETURN_PAGE,P721_SPL_SET_ID,P721_SPL_ROOT_ID,P721_CERT_COUNT,P721_VERSION_NUM,P721_SETVERSION_NUM,P721_LISTING_ID,P721_PROD_NDC:501,0cb2ee04-8581-46c8-a781-7be170ab5c86,2a69cbe0-e68c-4bc3-be8b-b8d72f3eed5a,0,6,6,1186723,81520-255

- in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults.
- in combination with amoxicillin for the treatment of H. pylori infection in adults.

- Route of Administration: oral
- Dosage Form: tablets
- Strength: 10 mg and 20 mg
- Dose and Frequency:

Indication	Recommended Dosage and Regimen	Duration
Healing of Erosive Esophagitis and Relief of Heartburn	VOQUEZNA 20 mg once daily	8 weeks
Maintenance of Healed Erosive Esophagitis and Relief of Heartburn	VOQUEZNA 10 mg once daily	Up to 6 months
Treatment of *H. pylori* Infection		
Triple Therapy	VOQUEZNA 20 mg twice daily	14 days
	Amoxicillin 1,000 mg twice daily	14 days
	Clarithromycin 500 mg twice daily	14 days
Dual Therapy	VOQUEZNA 20 mg twice daily	14 days
	Amoxicillin 1,000 mg three times daily	14 days

- How Supplied: 30 count bottles
- Storage: Store between 20°C to 25°C (68°F to 77°F). Brief exposure to 15°C to 30°C (59°F to 86°F) permitted [see USP Controlled Room Temperature].

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Voquezna 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 Voquezna. The Division of Gastroenterology (DG) declined to respond with the findings of OPDP's assessment for Voquezna.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Phathom did not provide a derivation or intended meaning for the proposed proprietary name, Voquezna, in their submission.

This proprietary name is comprised of a single word that contains the letters ‘vo’ in the prefix of the name, which is the abbreviation for ‘verbal order’.

We typically discourage the inclusion of medical abbreviations in proprietary names; however, we evaluated the potential risk of misinterpreting the proposed proprietary name Voquezna as “VO Quezna”, with “VO” as a modifier. A POCA search of the name “Quezna” did not identify any names that would pose a risk for confusion. Furthermore, the letters ‘vo’ are not separated from the name, capitalized, or bolded, to make the letters ‘vo’ more prominent in the name. Thus, we do not object to the inclusion of the letters 'vo' in this case. Beyond this abbreviation, we note that Voquezna does not contain any other additional components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

As previously noted, Voquezna the root name is already approved as of May 3, 2022, though to our knowledge, it has not yet been marketed.[e]

2.2.3 Comments from Other Review Disciplines at Initial Review

Division of Gastroenterology (DG) did not forward any comments or concerns relating to Voquezna at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Nintey (n=90) practitioners participated in DMEPA’s prescription studies for Voquezna. 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.

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[d]USAN stem search conducted on July 5, 2023.

[e]Voquezna Dual Pak and Voquezna Tripak will be marketed on November 30, 2023. Available at: https://dqcp.fda.gov/dqcp/f?p=1105:721:300811018828791::NO::P721_RETURN_PAGE,P721_SPL_SET_ID,P721_SPL_ROOT_ID,P721_CERT_COUNT,P721_VERSION_NUM,P721_SETVERSION_NUM,P721_LISTING_ID,P721_PROD_NDC:501,0cb2ee04-8581-46c8-a781-7be170ab5c86,2a69cbe0-e68c-4bc3-be8b-b8d72f3eed5a,0,6,6,1186723,81520-255

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[f] identified 22 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review. We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that the duration of therapy under the EE indication has changed (b) (4) to 8 weeks during the last review cycle; however, we determined this does not alter our previous conclusion regarding the acceptability of the name. We agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 2 names not previously analyzed. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

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

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

Similarity Category	Number of Names
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 none of the names will pose a risk for confusion with Voquezna as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On July 31, 2023, DMEPA 1 communicated our determination to the Division of Gastroenterology (DG).

3 CONCLUSION

The proposed proprietary name, Voquezna, is conditionally acceptable.

[f] POCA search conducted on in version 5.2

If you have any questions or need clarifications, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

3.1 COMMENTS TO PHATHOM PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on May 19, 2023, are altered prior to approval of the marketing application, the name must be resubmitted for review.

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. 6F[g]

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

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

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

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, 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 names7F[h]. 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.

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

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

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

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

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

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

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

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

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

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

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength

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

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

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

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

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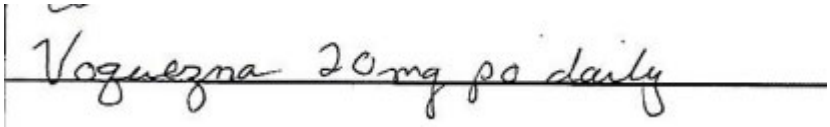
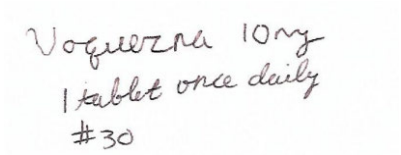
Appendix B: Prescription Simulation Samples and Results

Figure 1. Voquezna Study (Conducted on July 5, 2023)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Voquezna 10 mg 1 tablet once daily #30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Voquezna	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Voquezna

People Received Study: 254

People Responded: 90

Total	21	25	18	26	90
INTERPRETATION	**INPATIENT**	**OUTPATIENT**	**VOICE**	**CPOE**	**TOTAL**
LOQUEZNA	0	0	1	0	1
THOQUESNA	0	0	1	0	1
VOQEZNA	0	0	1	0	1
VOQUENZA	1	0	0	0	1
VOQUERNA	0	12	0	0	12

VOQUESNA	0	0	3	0	3
VOQUEZMA	1	0	0	0	1
VOQUEZNA	19	11	12	26	68
VOQUEZRA	0	1	0	0	1
VOQURENA	0	1	0	0	1

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

No.	**Proposed name:** Voquezna **Established name:** vonoprazan **Dosage form:** tablets **Strength(s):** 10 mg and 20 mg **Usual Dose:** 10 mg once daily and 20 mg once or twice daily	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Voquezna	100	Name subject of 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-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-N/A

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

No.	Name	POCA Score (%)
1.	(b) (4) ***	58

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

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/

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PROPRIETARY NAME REVIEW

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

Date of This Review:	April 26, 2022
Application Type and Number:	NDA 215151 Voquezna NDA 215153 Voquezna Dual Pak NDA 215152 Voquezna Triple Pak
Product Name and Strength:	Voquezna (vonoprazan fumarate) Tablets, 10 mg and 20 mg Voquezna Dual Pak (vonoprazan fumarate and amoxicillin) vonoprazan tablets, 20 mg and amoxicillin capsules, 500 mg Voquezna (vonoprazan fumarate, amoxicillin, and clarithromycin) vonoprazan tablets, 20 mg; amoxicillin capsules, 500 mg; and clarithromycin tablets, 500 mg
Product Type:	Single Ingredient Product (Voquezna) Multiple Ingredient, Co-Packaged Products (Voquezna Dual Pak and Voquezna Triple Pak)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Phathom Pharmaceuticals, Inc. (Phathom)
PNR ID #:	2022-1044724493 (Voquezna) 2022-1044724481 (Voquezna Dual Pak) 2022-1044724480 (Voquezna Triple Pak)
DMEPA 1 Safety Evaluator:	Deborah Myers, RPh, MBA
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Associate Director for Nomenclature and Labeling:	Mishale Mistry, PharmD, MPH

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Phathom previously submitted the proposed proprietary names, [(b) (4)]***, [(b) (4)] Dual Pak*** and [(b) (4)] Triple Pak*** on August 28, 2020. We found the names, [(b) (4)]***, [(b) (4)] Dual Pak*** and [(b) (4)] Triple Pak*** acceptable under INDs 079212, 144399 and 143190, respectively, on February 12, 2021.[a]

On September 21, 2021, under NDAs 215153 and 215152, Phathom submitted the names, [(b) (4)] Dual Pak*** and [(b) (4)] Triple Pak***, respectively, for review and estimated their expected submission of their NDA for the root name, [(b) (4)]***, under NDA 215151 during the fourth quarter of 2022. We found the names, [(b) (4)] Dual Pak*** and [(b) (4)] Triple Pak*** acceptable under NDAs 215153 and 215152, respectively, on December 3, 2021.[b] However, on January 11, 2022, Phathom submitted their Proprietary Name Withdrawal Request for the proprietary names [(b) (4)]***, [(b) (4)] Dual Pak***, and [(b) (4)] Triple Pak*** under IND 079212, NDA 215153 and NDA 215152, respectively. Concurrently on January 11, 2022, Phathom submitted the proposed proprietary names [(b) (4)]***, [(b) (4)] Dual Pak***, and [(b) (4)] Triple Pak*** for review under IND 079212, NDA 215153, and NDA 215152, respectively. We found the names, [(b) (4)]***, [(b) (4)] Dual Pak***, and [(b) (4)] Triple Pak***, unacceptable under IND 079212, NDA 215153, and NDA 215152, respectively, on March 9, 2022[c] and the associated Proprietary Name Request Unacceptable letters were sent on

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[a] Myers, D. Proprietary Name Review for [(b) (4)], [(b) (4)] Dual Pak, and [(b) (4)] Triple Pak (INDs 079212, 144399, and 143190). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 FEB 12. PNR ID Nos. 2020-41831928, 2020-42458721, and 2020-42458679.

[b] Myers, D. Proprietary Name Review for [(b) (4)] Dual Pak and [(b) (4)] Triple Pak (NDAs 215153 and 215152). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 DEC 03. PNR ID Nos. 2021-1044724197 and 2021-1044724196.

[c] Myers, D. Proprietary Name Review for [(b) (4)], [(b) (4)] Dual Pak and [(b) (4)] Triple Pak (IND 079212, NDA 215153, and NDA 215152). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2022 MAR 09. PNR ID Nos. 2022-1044724388, 2022-1044724383, and 2022-1044724387.

March 11, 2022.[d,e,f] Therefore, on March 11, 2022, Phathom submitted their Proprietary Name Withdrawal Request for the proprietary names (b) (4) Dual Pak*** and (b) (4) Triple Pak*** and concurrently submitted their proposed proprietary names Voquezna Dual Pak and Voquezna Triple Pak for review under NDAs 215153 and 215152, respectively.

We note that Phathom also submitted their proposed proprietary name, (b) (4)***, under NDA 215151 on March 11, 2022. However, given that the name was previously found unacceptable under IND 079212, on March 17, 2022, Phathom submitted their Proprietary Name Withdrawal Request for the proprietary name (b) (4)*** and concurrently submitted their proposed proprietary name Voquezna for review under NDA 215151.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submissions received on March 11, 2022 (Voquezna Dual Pak and Voquezna Triple Pak) and March 17, 2022 (Voquezna).

Table 1. Product Information for the Proposed Proprietary Names

	Voquezna	Voquezna Dual Pak	Voquezna Triple Pak
Application Type and Number	NDA 212151	NDA 215153	NDA 215152
Intended Pronunciation	voe kwez' nah	voe kwez' nah dool pak	voe kwez' nah tri pl pak
Active Ingredient	vonoprazan fumarate	vonoprazan fumarate and amoxicillin	vonoprazan fumarate, amoxicillin, and clarithromycin
Indication of Use	Healing of all grades of erosive esophagitis and relief of heartburn. Maintenance of healing of all grades of erosive esophagitis	Treatment of *H. pylori* infection	

[d] Dunson, A. FDA Communication: Proprietary Name Request Unacceptable letter for (b) (4) (IND 079212). Silver Spring (MD): FDA, CDER, OSE (US); 2022 MAR 11. IND 079212. Available at: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8064dcec.

[e] Chung A. FDA Communication: Proprietary Name Request Unacceptable letter for (b) (4) Dual Pak (NDA 215153). Silver Spring (MD): FDA, CDER, OSE (US); 2022 MAR 11. NDA 215153. Available at: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8064de20.

[f] Chung A. FDA Communication: Proprietary Name Request Unacceptable letter for (b) (4) Triple Pak (NDA 215152). Silver Spring (MD): FDA, CDER, OSE (US); 2022 MAR 11. NDA 215152. Available at: https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8064dc29.

	and relief of heartburn. Treatment of *H. pylori* infection.		
Route of Administration	Oral		
Dosage Form	Tablets	Tablets and Capsules	
Strength	10 mg and 20 mg	vonoprazan fumarate tablets, 20 mg and amoxicillin capsules, 500 mg	vonoprazan fumarate tablets, 20 mg, amoxicillin capsules, 500 mg, and clarithromycin tablets, 500 mg
Dose and Frequency	**Healing of all grades of erosive esophagitis and relief of heartburn**: 20 mg once daily for (b) (4) 8 weeks **Maintenance of healing of all grades of erosive esophagitis and relief of heartburn**: 10 mg once daily for up to 6 months **Treatment of *H. pylori* infection**: Triple Therapy: vonoprazan 20 mg 2 times a day, amoxicillin 1,000 mg 2 times a day, clarithromycin 500 mg 2 times a day for 14 days Dual Therapy: vonoprazan 20 mg 2 times a day and amoxicillin 1,000 mg 3 times a day for 14 days	**Dual therapy**: vonoprazan 20 mg 2 times a day and amoxicillin 1,000 mg 3 times a day	**Triple therapy**: vonoprazan 20 mg 2 times a day, amoxicillin 1,000 mg 2 times a day, clarithromycin 500 mg 2 times a day

How Supplied	10 mg: 30 count bottles, (b) (4) [redacted] 20 mg: 30 count bottles, 5 count bottles (sample)	Cartons containing 14 unit dose blister packages: Each blister card contains 2 vonoprazan 20 mg tablets and 6 amoxicillin 500 mg capsules.	Cartons containing 14 unit dose blister packages: Each blister card contains 2 vonoprazan 20 mg tablets, 4 amoxicillin 500 mg capsules, and 2 clarithromycin 500 mg tablets
Storage	Store between 20°C to 25°C (68°F to 77°F). Brief exposure to 15°C to 30°C (59°F to 86°F) permitted [see USP Controlled Room Temperature].	Store between 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature].	Store between 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from light.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak would not misbrand the proposed products. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Gastroenterology (DG) concurred with the findings of OPDP's assessment for Voquezna and the Division of Anti-Infectives (DAI) concurred with OPDP's assessments for Voquezna Dual Pak and Voquezna Triple Pak.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

[g] USAN stem search conducted on March 17, 2022.

2.2.2 Components of the Proposed Proprietary Name

Phathom did not provide a derivation or intended meaning for the proposed proprietary name, Voquezna, in their submission. This proprietary name is comprised of a single word. We note that Voquezna includes the letter string '-ue-,' a medical abbreviation for "upper extremity." In some circumstances, the incorporation of medical abbreviations in proprietary names can inadvertently be a source of error.[h] Although we typically discourage the inclusion of medical abbreviations in proprietary names, we determined that the locations of the abbreviation, 'ue' in the infix of the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion in this case. Thus, in this case, we do not object to the inclusion of the letter string 'ue' in the infix of the proposed proprietary name.

Phathom did not provide a derivation for their proposed proprietary names, Voquezna Dual Pak and Voquezna Triple Pak, in their submissions. However, Phathom included in their submissions that the proposed proprietary name, Voquezna Dual Pak, references the two ingredients (vonoprazan fumarate and amoxicillin) packaging configuration. This proprietary name is comprised of the root name, Voquezna, and the modifier "Dual Pak." Additionally, Phantom included in their submission that the proposed proprietary name, Voquezna Triple Pak, references the three ingredients (vonoprazan fumarate, amoxicillin, clarithromycin) packaging configuration. This proprietary name is comprised of the root name, Voquezna, and the modifier "Triple Pak." We assess the modifiers, "Dual Pak" and "Triple Pak," below in *Section 2.2.8*.

2.2.3 Comments from Other Review Disciplines at Initial Review

On April 8, 2022, the Division of Gastroenterology (DG) did not forward any comments or concerns relating to Voquezna, and on March 24, 2022, the Division of Anti-Infectives (DAI) did not forward any comments or concerns relating to Voquezna Dual Pak and Voquezna Triple Pak at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

a. Voquezna

One hundred three practitioners participated in DMEPA's prescription studies for Voquezna. 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. We note, in the voice simulation study that of the 28 participants; 4 interpreted the first syllable as 'Lo' and 1 interpreted the first syllable as 'Zo.' We have considered this variation in our analysis.

To determine if there are names that begin with the sounds, 'Lo' and 'Zo' that could be a source of confusion with the root name, Voquezna, we considered this phonetic similarity in our analysis of the names identified in our search of the POCA system. Appendix B, Figure 1, contains the results from the prescription simulation studies.

b. Voquezna Dual Pak

[h] Draft Guidance for Industry: Best Practices in Developing Proprietary Names for Drugs. 2014. Available from: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm398997.pdf.

One hundred four practitioners participated in DMEPA's prescription studies for Voquezna Dual Pak. 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.

We note, in the voice simulation study that of the 23 participants; 10 interpreted the first syllable as 'Lo'. We have considered this variation in our analysis. Additionally, 9 of these 10 incorrect root name interpretations did however include the modifier "dual pak" (5 correctly interpreted the modifier as "Dual Pak", and 1 each interpreted the modifier as "Duo Pack", "Dual Pakl", "Dual Pack", and "Dualpak"). Thus, the correct interpretation of the modifier may help to decrease the risk of name confusion and wrong product medication errors.

To determine if there are names that begin with the sound, 'Lo' that could be a source of confusion with the root name, Voquezna, we considered this phonetic similarity in our analysis of the names identified in our search of the POCA system (see Appendix E). Appendix B, Figure 2, contains the results from the prescription simulation studies.

c. Voquezna Triple Pak

One hundred two practitioners participated in DMEPA's prescription studies for Voquezna Triple Pak. 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.

We note, in the voice simulation study that of the 22 participants; 2 interpreted the first syllable as 'Lo' and 1 interpreted the first syllable as 'Zo.' We have considered these variations in our analysis. Additionally, all three of these three incorrect root name interpretations did however include the modifier "Triple Pak" (two interpreted the modifier as "Triple Pack"). Thus, the correct interpretation of the modifier may help to decrease the risk of name confusion and wrong product medication errors.

To determine if there are names that begin with the sounds, 'Lo' and 'Zo' that could be a source of confusion with the root name, Voquezna, we considered this phonetic similarity in our analysis of the names identified in our search of the POCA system (see Appendix E). Appendix B, Figure 3, contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[i] identified 21 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

[i] POCA search conducted on March 17, 2022 in version 4.4.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 2 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 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	20
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 21 names contained in Table 2 determined none of the names will pose a risk for confusion with Voquezna as described in Appendices C through H.

2.2.8 Safety Assessment of the Proposed Modifiers, "Dual Pak" and "Triple Pak"

a. Dual Pak

Phantom indicated in their submission that the proposed proprietary name, Voquezna Dual Pak, references the two-ingredient (vonoprazan fumarate and amoxicillin) packaging configuration.

To determine if the modifier, "Dual Pak" is currently utilized, we searched our internal databases and did not identify any completed proprietary name reviews for names that contain this modifier. Additionally, we searched Drugs@FDA and identified the proprietary name "Monistat Dual-Pak" that contain this modifier. Monistat Dual-Pak (NDA 020968) was approved on June 30, 1999 and is listed as a discontinued product on Drugs@FDA. However, our search of Drugs@FDA identified inclusion of the modifier "Pak" in the approved proprietary names, Kitabis Pak, Trovan/Zithromax Compliance Pak (listed as a discontinued product), and Viekira Pak, as well as part of the proprietary name, Lymepak. We then searched the Institute for Safe Medication Practices' (ISMP) List of Products with Drug Name Suffixes and found that the "Dual Pak" modifier does not currently exist in drug nomenclature; however, the modifier "pak", which has been commonly used as a drug name suffix to convey a blister packaging configuration is

included.[j] We also note that neither "Dual Pak" or "Pak" is included on ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations.[k]

It is not uncommon to use modifiers to denote a specific formulation or packaging configuration as part of a product line extension. The addition of a modifier "Dual Pak" to the root name Voquezna may help to differentiate the proposed two-ingredient (vonoprazan fumarate and amoxicillin) packaging configuration from the other products within the Voquezna product line. However, we also note that omission and oversight of a modifier is cited in literature as a common cause of medication error.[l] Postmarketing experience shows medication errors if the modifier is omitted and the product characteristics are similar or overlap. In this instance, if the modifier were omitted, a pharmacist would have to seek clarification as there are two strengths of Voquezna tablets alone and two "Pak" packaging configurations from which to select.

We find that the proposed modifier "Dual Pak" can convey that there is a difference between the proposed products, Voquezna and Voquezna Triple Pak, and is consistent with its intended meaning. Thus, we find the proposed "Dual Pak" modifier acceptable from a medication error perspective. Furthermore, any residual risks of confusion between the currently marketed and proposed products can be managed with labeling mitigation strategies that will be conveyed on our Label and Labeling review.

b. Triple Pak

Phantom indicated in their submission that the proposed proprietary name, Voquezna Triple Pak, references the three ingredients (vonoprazan fumarate, amoxicillin, and clarithromycin) packaging configuration.

To determine if the modifier, "Triple Pak" is currently utilized, we searched our internal databases and did not identify any completed proprietary name reviews for names that contain this modifier. Additionally, we searched Drugs@FDA and again did not identify any proprietary names that contain this modifier. However, our search of Drugs@FDA identified inclusion of the modifier "Pak" in the approved proprietary names, Kitabis Pak, Trovan/Zithromax Compliance Pak (listed as a discontinued product), and Viekira Pak, as well as part of the proprietary name, Lymepak. We then searched the Institute for Safe Medication Practices' (ISMP) List of Products with Drug Name Suffixes and found that the "Triple Pak" modifier does not currently exist in drug nomenclature; however, the modifier "pak", which has been commonly used as a drug name suffix to convey a blister

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[j] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf.

[k] ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2017. Available from: https://www.ismp.org/recommendations/error-prone-abbreviations-list.

[l] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

packaging configuration is included.[m] We also note that neither "Triple Pak" or "Pak" is included on ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations.[n]

It is not uncommon to use modifiers to denote a specific formulation or packaging configuration as part of a product line extension. The addition of a modifier "Triple Pak" to Voquezna may help to differentiate the proposed three ingredients (vonoprazan fumarate, amoxicillin, and clarithromycin) packaging configuration. However, we also note that omission and oversight of a modifier is cited in literature as a common cause of medication error.[o] Postmarketing experience shows medication errors if the modifier is omitted and the product characteristics are similar or overlap. In this instance, if the modifier were omitted, a pharmacist would have to seek clarification as there are two strengths of Voquezna tablets alone and two "Pak" packaging configurations from which to select.

We find that the proposed modifier "Triple Pak" can convey that there is a difference between the proposed products, Voquezna and Voquezna Dual Pak, and is consistent with its intended meaning. Thus, we find the proposed "Triple Pak" modifier acceptable from a medication error perspective. Furthermore, any residual risks of confusion between the currently marketed and proposed products can be managed with labeling mitigation strategies that will be conveyed on our Label and Labeling review.

2.2.9 Communication of DMEPA's Determination

On April 24, 2022, DMEPA 1 communicated our determinations to the Division of Gastroenterology (DG) and the Division of Anti-Infectives (DAI).

3 CONCLUSION

The proposed proprietary names, Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak, are acceptable.

If you have any questions or need clarifications regarding the proposed proprietary name, Voquezna, please contact Alvis Dunson, OSE project manager, at 301-796-6400.

If you have any questions or need clarifications regarding the proposed proprietary names, Voquezna Dual Pak and Voquezna Triple Pak, please contact Amy Chung, OSE project manager, at 240-402-4547.

3.1 COMMENTS TO PHATHOM PHARMACEUTICALS, INC.

[m] ISMP's List of Products with Drug Name Suffixes [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2010. Available from: https://www.ismp.org/sites/default/files/attachments/2018-04/drugnamesuffixes.pdf.

[n] ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations [Internet]. Horsham (PA): Institute for Safe Medication Practices. 2017. Available from: https://www.ismp.org/recommendations/error-prone-abbreviations-list.

[o] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

We have completed our review of the proposed proprietary names, Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your submissions, received on March 11, 2022 (Voquezna Dual Pak and Voquezna Triple Pak) and March 17, 2022 (Voquezna) are altered prior to approval of the marketing application, the names 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. [p]

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

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

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

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

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

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

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

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

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

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.

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

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

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

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

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

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

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

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

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

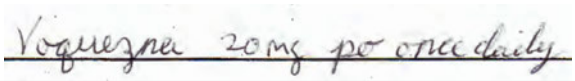
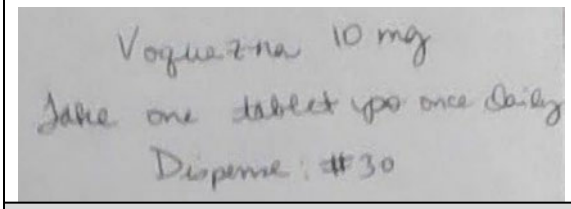
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Voquezna Study (Conducted on March 25, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Voquezna 10 mg Take one tablet by mouth once daily Dispense: #30
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Voquezna	

FDA Prescription Simulation Responses (Aggregate Report)

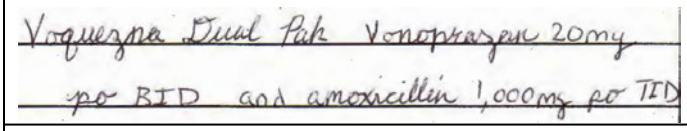
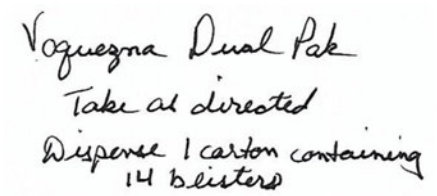
263 People Received Study
103 People Responded

Study Name: Voquezna

Total	**24**	**26**	**28**	**25**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
DELQUEZNA	0	0	1	0	1
LOQUEZNA	0	0	4	0	4
VAQUEZNA	0	0	0	2	2
VOGUEZNA	0	0	0	1	1
VOKENA	0	0	1	0	1
VOPLESZNA	0	0	1	0	1
VOQEZNA	0	0	1	0	1
VOQUENZA	1	0	0	0	1
VOQUENZA 10 MG	0	0	1	0	1
VOQUESNA	0	0	1	0	1
VOQUEZNA	22	26	17	14	79

VOQUEZNE	0	0	0	2	2
VOQUEZNEI	0	0	0	4	4
VOQUEZNER	0	0	0	1	1
VOQUZENA	0	0	0	1	1
VOQUZUA	1	0	0	0	1
ZOLESNA	0	0	1	0	1

Figure 2. Voquezna Dual Pak Study (Conducted on March 18, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Voquezna Dual Pak Take as directed. Dispense 1 carton containing 14 blisters
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Voquezna Dual Pak	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
104 People Responded

Study Name: Voquezna Dual Pak

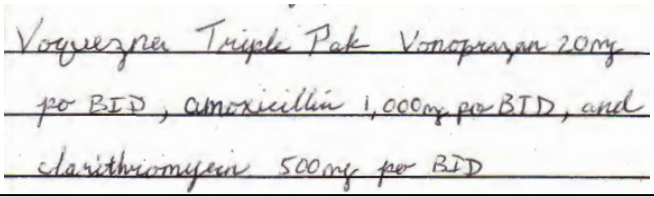
Total	**22**	**29**	**23**	**30**

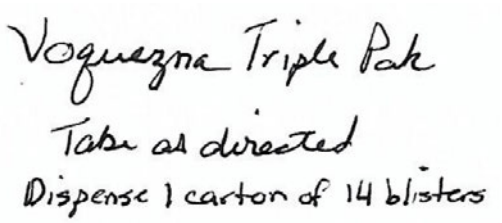
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
LOQUESNA	0	0	1	0	1
LOQUESNA DUAL PAK	0	0	1	0	1
LOQUESNA DUO PACK	0	0	1	0	1
LOQUESNO DUAL PAK	0	0	1	0	1

LOQUESZNA DUAL PAKL	0	0	1	0	1
LOQUEZNA DUAL PACK	0	0	1	0	1
LOQUEZNA DUAL PAK	0	0	2	0	2
LOQUEZNA DUALPAK	0	0	1	0	1
LOQUEZNO DUAL PAK	0	0	1	0	1
MOQUESNA DUAL PACK	0	0	1	0	1
NOQUESNA DUAL PAK	0	0	1	0	1
OQUESDA DUAL PACK	0	0	1	0	1
VAQUEZNA DUAL PACK	1	0	0	0	1
VOGUEZNA DUAL PAK VONOPRAGEN	0	0	0	1	1
VOQUEGNA DUAL PAK	3	0	0	0	3
VOQUENZA DUAL PAK	1	0	0	0	1
VOQUENZA DUAL PAK VONOPRAZEN 20MG	0	0	0	1	1
VOQUERZNA DUAL PAK	0	0	0	1	1
VOQUESNA	0	0	2	0	2
VOQUESNA DUAL PACK	0	0	4	0	4
VOQUEZMA DUAL PAK	1	0	0	0	1
VOQUEZNA	1	0	1	2	4
VOQUEZNA DUAL PACK	0	0	2	1	3
VOQUEZNA DUAL PAK	15	29	1	10	55
VOQUEZNA DUAL PAK (VONOPRAZAN)	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRASYN W/ AMOXICILLIN	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZAN	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZAN AND AMOXICILLIN	0	0	0	1	1

VOQUEZNA DUAL PAK VONOPRAZEN	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZEN 20MG PO BID AND AMOXICILLIN 1000 MG PO TID	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZER	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZER & AMOXICILLIN	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZPEN	0	0	0	1	1
VOQUEZNA DUAL PAK VONOPRAZYN AND AMOXICILLIN	0	0	0	1	1
VOQUEZNA DUAL-PACK	0	0	0	1	1
VOQUEZRA DUAL PACK VONOPRAZEN AND AMOXICILLIN	0	0	0	1	1
VOQUEZRA DUAL PAK	0	0	0	1	1
VOQUEZRA DUAL PAK VONOPRASGEN	0	0	0	1	1

Figure 3. Voquezna Triple Pak Study (Conducted on March 22, 2022)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Voquezna Triple Pak Take as directed. Dispense 1 carton of 14

Outpatient Prescription:  	blisters
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Voquezna Triple Pak	

FDA Prescription Simulation Responses (Aggregate Report)

262 People Received Study
102 People Responded

Study Name: Voquezna Triple Pak

Total	**25**	**29**	**22**	**26**	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
LOQUENZA TRIPLE PACK	0	0	2	0	2
THOQUENZA TRIPLE PACK	0	0	1	0	1
VELQUENZA TRIPLE PACK	0	0	2	0	2
VIOQUENZA TRIPLE PACK	0	0	1	0	1
VOLQUENZA TRIPLE PACK	0	0	1	0	1
VOQUENZA	0	0	2	0	2
VOQUENZA TRIPLE PACK	0	0	9	0	9
VOQUENZA TRIPLE PAK	0	0	1	0	1
VOQUENZA TRIPLEPAK	0	0	1	0	1
VOQUEZMA TRIPLE PAK	4	0	0	0	4
VOQUEZNA	1	0	0	1	2

VOQUEZNA TRIPLE PACK	2	0	0	0	2
VOQUEZNA TRIPLE PAK	18	29	0	10	57
VOQUEZNA TRIPLE PAK VONOPRAZAN AMOXICILLIN CLARITHROMYCIN	0	0	0	1	1
VOQUEZNER TRIPLE PAK	0	0	0	2	2
VOQUEZNER TRIPLE PAK, VONOPRAZAN, AMOXICILLIN, CLARITHROMYCIN	0	0	0	1	1
VOQUEZORER TRIPLE PAK	0	0	0	1	1
VOQUEZRA TRIPLE PACK	0	0	0	1	1
VOQUEZRA TRIPLE PAK	0	0	0	1	1
VOQUEZRA TRIPLE PAK (VONOPRAZAN, AMOXICILLIN, CLARITHROMYCIN	0	0	0	1	1
VOQUEZRA TRIPLE PAK VONOPRAZAR, AMOXICILLIN, CLARITHROMYCIN	0	0	0	1	1
VOQUEZRA TRIPLE PAK VONOPRESAN, AMOXICILLAN, CLARITHROMYCIN	0	0	0	1	1
VOQUEZRA TRIPLE PAK VONOPREZOR 20 MG, AMOXICILLIN 1000 MG AND CLARITHROMYCIN 500 MG	0	0	0	1	1
VOQUEZREI TRIPLE PAK	0	0	0	1	1
VOQUEZREI TRIPLE PAK VONOPERZAN 20 MG, AMOXICILLIN 1000	0	0	0	1	1

MG, CLARITHROMYCIN 500 MG					
VOQUEZRU TRIPLE PAK	0	0	0	1	1
VOQUINZA TRIPLE PACK	0	0	1	0	1
VOQUQORA TRIPLE PAK VONOPREZAR	0	0	0	1	1
ZOQUENZA TRIPLE PAK	0	0	1	0	1

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

No.	**Proposed name:** Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak **Established name:** vonoprazan fumarate, vonoprazan fumarate and amoxicillin, and vonoprazan fumarate, amoxicillin, and clarithromycin **Dosage form:** Tablets, Tablets and Capsules, and Tablets, Capsules, and Tablets **Strength(s):** 10 mg and 20 mg, Dual Pak: 20 mg and 500 mg, Triple Pak: 20 mg, 500 mg, and 500 mg **Usual Dose:** Voquezna: One tablet once daily OR 2 times a day.	**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.	Voquezna	100	Name is the root name 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.	Qutenza	58
2.	Vonvendi	58
3.	Voluven	57

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:** Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak **Established name:** vonoprazan fumarate, vonoprazan fumarate and amoxicillin, and vonoprazan fumarate, amoxicillin, and clarithromycin **Dosage form:** Tablets, Tablets and Capsules, and Tablets, Capsules, and Tablets **Strength(s):** 10 mg and 20 mg, Dual Pak: 20 mg and 500 mg, Triple Pak: 20 mg, 500 mg, and 500 mg **Usual Dose:** Voquezna: One tablet once daily OR 2 times a day.	**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.	(b) (4) ***	68	Orthographically, the prefixes (Vo- vs. (b) (4)) provide sufficient orthographic differences. Phonetically, the first (voe vs. (b) (4)) provides sufficient phonetic differences. Additionally, the product characteristics between the name pairs are different, which may provide additional mitigation, if included. There is no numerical overlap or similarity in strengths when comparing Voquezna (10 mg and 20 mg), Voquezna Dual Pak (20 mg and 500 mg), and Voquezna Triple Pack (20 mg, 500 mg and 500 mg) vs. (b) (4) . When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.

No.	**Proposed name:** Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak **Established name:** vonoprazan fumarate, vonoprazan fumarate and amoxicillin, and vonoprazan fumarate, amoxicillin, and clarithromycin **Dosage form:** Tablets, Tablets and Capsules, and Tablets, Capsules, and Tablets **Strength(s):** 10 mg and 20 mg, Dual Pak: 20 mg and 500 mg, Triple Pak: 20 mg, 500 mg, and 500 mg **Usual Dose:** Voquezna: One tablet once daily OR 2 times a day.	**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**
2.	(b) (4)***	68	Orthographically, the infixes (the downstrokes of the letters -q- and -z- if scripted in -quez- vs. (b) (4) and the suffixes (the downstroke of the letter -z- if scripted in -zna vs. (b) (4)) provide sufficient orthographic differences. Phonetically, the second syllables (kwez vs. (b) (4)) provided sufficient phonetic differences. Additionally, the product characteristics between the name pairs are different, which may provide additional mitigation, if included. There is no numerical overlap or similarity in strengths (10 mg and 20 mg), Voquezna Dual Pak (20 mg and 500 mg), and Voquezna Triple Pack (20 mg, 500 mg and 500 mg) vs. (b) (4) or final dose (10 mg and 20 mg vs. (b) (4) (b) (4)

No.	**Proposed name:** Voquezna, Voquezna Dual Pak, and Voquezna Triple Pak **Established name:** vonoprazan fumarate, vonoprazan fumarate and amoxicillin, and vonoprazan fumarate, amoxicillin, and clarithromycin **Dosage form:** Tablets, Tablets and Capsules, and Tablets, Capsules, and Tablets **Strength(s):** 10 mg and 20 mg, Dual Pak: 20 mg and 500 mg, Triple Pak: 20 mg, 500 mg, and 500 mg **Usual Dose:** Voquezna: One tablet once daily OR 2 times a day.	**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**
			(b) (4) (b) (4) Also, we note that the route of administration (oral vs. (b) (4)) and dosage form (tablet vs. (b) (4)) differ, if included on a prescription. When all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case.
3.	Vegzelma***	61	This name pair has sufficient orthographic and phonetic differences.
4.	(b) (4) ***	60	This name pair has sufficient orthographic and phonetic differences.
5.	Anoquan	56	This name pair has sufficient orthographic and phonetic differences.
6.	Uplizna	56	This name pair has sufficient orthographic and phonetic differences.
7.	Moxeza	56	This name pair has sufficient orthographic and phonetic differences.
8.	Nocdurna	56	This name pair has sufficient orthographic and phonetic differences.
9.	Voquezna Dual Pak***	56	Name is included as a subject of this review.

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

No.	Name	POCA Score (%)
1.	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.	(b) (4) ***	60	Proposed proprietary name for BLA 761143 found to be conditionally acceptable (OSE # 2019-34178516, dated 11/25/2019). Subsequently, on 01/13/2020 this proposed proprietary name was withdrawn by the Applicant. BLA 761143 was approved on 01/21/2020 under the proprietary name, Tepezza.
2.	(b) (4) ***	59	Proposed proprietary name for IND 121691 found to be acceptable (OSE # 2019-29122936, dated 3/14/2019). This proposed proprietary name was withdrawn by the Applicant on 7/08/2019. NDA 213137 approved under the proprietary name, Oxbryta, on November 25, 2019.
3.	(b) (4) ***	56	Proposed proprietary name under IND (b) (4) withdrawn by the Applicant on (b) (4). Subsequently, on (b) (4) the Applicant submitted a request to review the proposed proprietary name, (b) (4) ***, which was found to be conditionally acceptable (OSE# (b) (4) dated on (b) (4)). On (b) (4) the proposed proprietary name, (b) (4) *** was withdrawn. IND (b) (4) is pending and no new names have been submitted.
4.	Valturna	56	Brand discontinued with no generic equivalents available. NDA 022217 withdrawn FR effective 01/05/2015.

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

No.	Name	POCA Score (%)
1.	Equizone	57
2.	(b) (4) ***	57
3.	Levaquin	55
4.	Suprenza	55

[r] 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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