CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210136Orig1s000

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:	January 17, 2023
Application Type and Number:	NDA 210136
Product Name and Strength:	Brixadi (buprenorphine) extended-release injection Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/0.64 mL Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Braeburn Pharmaceuticals, Inc. (Braeburn)
PNR ID #:	2022-1044724857
DMEPA 1 Safety Evaluator:	Damon Birkemeier, PharmD
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, Brixadi, 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. Braeburn submitted an external name study dated November 21, 2017, conducted (b) (4) for this proposed proprietary name. The external study was evaluated in our previous review of the name.[a]

1.1 REGULATORY HISTORY

Braeburn previously submitted the proposed proprietary name, (b) (4)***, on October 11, 2016, under IND 114082. We found the name, (b) (4)*** conditionally acceptable on March 31, 2017.[b] However, Braeburn withdrew the proposed proprietary name (b) (4)*** on June 28, 2017. Thus, Braeburn submitted the name, (b) (4)***, for review on July 19, 2017. However, we found the name, (b) (4)*** unacceptable under NDA 210136 and IND 114082 on August 25, 2017, due to orthographic similarities, phonetic similarities and shared product characteristics with the proprietary names, (b) (4)[c] Thus, Braeburn submitted the name, Brixadi, for review on November 21, 2017. We found the name, Brixadi, conditionally acceptable on January 10, 2018.[a] On January 19, 2018, NDA 210136 was issued a Complete Response (CR) letter due to clinical, statistical, nonclinical, product quality, device, microbiology and drug product deficiencies. On May 23, 2018, Braeburn submitted a response to address the deficiencies outlined in FDA's January 19, 2018, CR letter.

On June 22, 2018, the resubmission of NDA 210136 was deemed incomplete, and an Acknowledge Incomplete Response Letter was issued to Braeburn.

On June 26, 2018, Braeburn submitted a Class 2 Resubmission to NDA 210136 to address the deficiencies identified in the June 22, 2018, Acknowledge Incomplete Response letter. In the Class 2 Resubmission, Braeburn also re-submitted the name, Brixadi, for review. We re-reviewed the proprietary name, Brixadi, and found the name conditionally acceptable on August 12, 2018.[d] On December 21, 2018, NDA 210136 received Tentative Approval under 21 CFR 314.105 with final approval subject to expiration of a period of patent protection and/or exclusivity.

On June 1, 2020, Braeburn submitted a Request for Final Approval for NDA 210136. However, on December 1, 2020, NDA 210136 received another CR due to a facility inspections deficiency.

---

[a] Shah, M. Proprietary Name Review for Brixadi*** (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 10. Panorama No. 2017-18773253.

[b] Shah, M. Proprietary Name Review for (b) (4)*** (IND 114082). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAR 31. Panorama No. 2016-10707590.

[c] Shah, M. Proprietary Name Review for (b) (4)*** (IND 114082 and NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 AUG 25. Panorama No. 2017-16036139 and 2017-16874573.

[d] Wilson, V. Proprietary Name Review for Brixadi*** (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 13. Panorama No. 2018-23538531.

On June 15, 2021, Braeburn submitted a response to address the facility inspection deficiency as a Class 2 Resubmission. In the Class 2 Resubmission, Braeburn also re-submitted the name, Brixadi, for review. We re-reviewed the proprietary name, Brixadi and found the name conditionally acceptable on September 7, 2021.[e] However, on December 15, 2021, NDA 210136 received another CR due to a facility inspections deficiency.

On November 23, 2022, Braeburn submitted a response to address the facility inspection deficiency as a Class 2 Resubmission. In the Class 2 Resubmission, Braeburn also re-submitted the name, Brixadi, which is the subject of this review.

1.2 PRODUCT INFORMATION

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

- Intended Pronunciation: brix a' dee
- Active Ingredient: buprenorphine
- Indication of Use: treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of transmucosal buprenorphine product or who are already being treated with buprenorphine
- Route of Administration: subcutaneous
- Dosage Form: extended-release injection
- Strength:
    - Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/ 0.64 mL
    - Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL
- Dose and Frequency: Inject 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL or 32 mg/0.64 mL subcutaneously once weekly; inject 64 mg/0.18 mL, 96 mg/0.27 mL or 128 mg/0.36 mL subcutaneously once monthly
- How Supplied: single dose, prefilled safety syringe
- Storage: USP Controlled Room Temperature
- Reference Listed Drug/Reference Product: Subutex (NDA 020732)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

[e] Clark C. Proprietary Name Review for Brixadi*** (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021 SEP 7. OSE RCM No. 202-1044724020.

The Office of Prescription Drug Promotion (OPDP) determined that Brixadi 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 Brixadi. The Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Brixadi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Braeburn did not provide a derivation or intended meaning for the proposed proprietary name, Brixadi, in their submission. This proprietary name is comprised of a single word. We note the proposed name contains the letter string "ad" which is a commonly used medical abbreviation meaning "right ear". Although we typically discourage the inclusion of medication abbreviations in the proprietary name, we determined that the location of the "ad" letter string in the infix of the name is unlikely to be separated from the surrounding letters in a manner that could lead to confusion. Thus, we do not object to the inclusion of the letter string "ad" in this case. Other than the abbreviation "ad", the proposed name, Brixadi, does not contain any components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication errors.

2.2.3 Comments from Other Review Disciplines at Initial Review

On December 13, 2022, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Brixadi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Ninety-three practitioners participated in DMEPA's prescription studies for Brixadi. We note that several participants in the verbal prescription study interpreted the proposed name, Brixadi, as beginning with an 'R' sound as opposed to a 'B' sound. For example, participants interpreted the name as Rexadi, Rexady, Rexati, Ricksaty, Rixaddy, Ryxadi, and Ryxady. However, 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.

[f] USAN stem search conducted on November 28, 2022.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[g] identified 144 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. We had identified some of the names in our previous proprietary name reviews. 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 none of the product characteristics have changed, and we agree with the findings from our previous reviews for the names evaluated previously. Therefore, we identified 11 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%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	10
Low similarity name pair: combined match percentage score ≤54%	1

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

Our analysis of the 11 names contained in Table 1 determined none of the names will pose a risk for confusion with Brixadi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Determination

On January 17, 2023, DMEPA 1 communicated our determination to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP).

3 CONCLUSION

The proposed proprietary name, Brixadi, is conditionally acceptable.

If you have any questions or need clarifications, please contact Ruth Maduro, OSE project manager, at 240-402-4232.

3.1 COMMENTS TO BRAEBURN PHARMACEUTICALS, INC.

[g] POCA search conducted on December 28, 2022 in version 5.0.

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

APPEARS THIS WAY ON ORIGINAL

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. [h]

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

[i] 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.

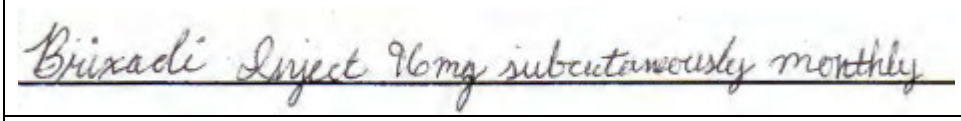
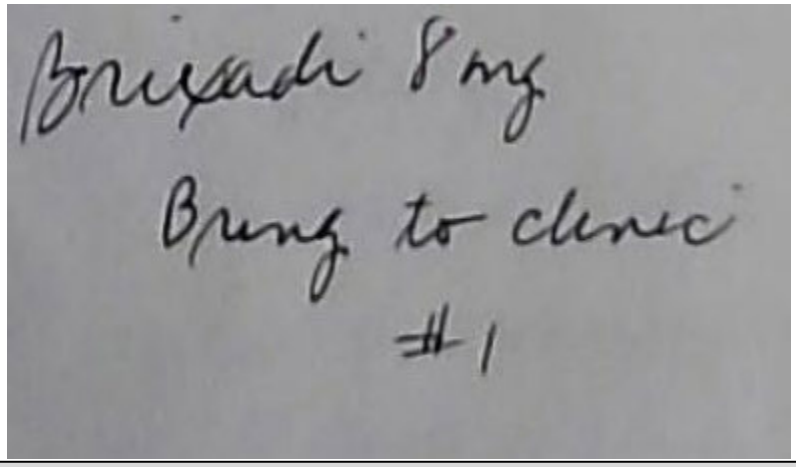
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Brixadi Study (Conducted on December 2, 2022)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  	Brixadi 8 mg Bring to Clinic #1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Brixadi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Brixadi

262 People Received Study

93 People Responded

Date of Study: December 2, 2022

Total	**24**	**26**	**20**	**23**	
INTERPRETATION	**INPATIENT**	**CPOE**	**VOICE**	**OUTPATIENT**	**TOTAL**
BREXATI	0	0	2	0	2
BRINSADRI	0	0	0	1	1
BRIXADDI	0	0	1	0	1
BRIXADDY	0	0	1	0	1

BRIXADE	1	0	0	0	1
BRIXADI	21	26	3	18	68
BRIXADI 8MG	0	0	0	1	1
BRIXADI INJECT	1	0	0	0	1
BRIXADRI	0	0	0	2	2
BRIXADY	0	0	1	0	1
BRIXALDI	0	0	0	1	1
BRIXATY	0	0	2	0	2
BRIZADI	1	0	0	0	1
REXADI	0	0	2	0	2
REXADY	0	0	2	0	2
REXATI	0	0	1	0	1
RICKSATY	0	0	1	0	1
RIXADDY	0	0	2	0	2
RYXADI	0	0	1	0	1
RYXADY	0	0	1	0	1

Appendix C: Highly Similar Names (e.g., combined POCA score is ≥70%) **--- N/A**

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.	Abrilada	68
2.	Braftovi	64
3.	Truxima	64
4.	(b) (4) ***	59
5.	Baqsimi	58
6.	Biktarvy	56
7.	(b) (4) ***	56

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:** Brixadi **Established name:** buprenorphine **Dosage form:** extended-release injection **Strength(s):** strength **Usual Dose:** Inject 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL or 32 mg/0.64 mL subcutaneously once weekly; inject 64 mg/0.18 mL, 96 mg/0.27 mL or 128 mg/0.36 mL subcutaneously once monthly	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.	Qbrexza	66	This name pair has sufficient orthographic and phonetic differences.
2.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.

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.	Pripsen	51	International drug product formerly marketed in Ireland and the United Kingdom.

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

No.	Name	POCA Score (%)
1.	(-)-Ambroxide	59

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

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

/s/

DAMON A BIRKEMEIER
01/17/2023 02:14:28 PM

VALERIE S VAUGHAN
01/17/2023 02:55:44 PM

MISHALE P MISTRY
01/17/2023 06:28:52 PM

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:	September 7, 2021
Application Type and Number:	NDA 210136
Product Name and Strength:	Brixadi (buprenorphine) extended-release injection, Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/ 0.64 mL Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Braeburn Pharmaceuticals, Inc. (Braeburn)
Panorama/PNR ID #:	2021-1044724020
DMEPA 1 Safety Evaluator:	Cameron Clark, PharmD
DMEPA 1 Team Leader:	Valerie S. Vaughan, PharmD
DMEPA 1 Division Director (Acting):	Irene Z. Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Brixadi, 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. Braeburn submitted an external name study dated November 21, 2017, conducted (b) (4) for this proposed proprietary name. The external study was evaluated in our previous review of the name.[a]

1.1 REGULATORY HISTORY

Braeburn previously submitted the proposed proprietary name, (b) (4)*** on October 11, 2016 under IND 114082. We found the name, (b) (4)*** conditionally acceptable on March 31, 2017.[b] However, Braeburn withdrew the proposed proprietary name (b) (4)*** on June 28, 2017. Thus, Braeburn submitted the name, (b) (4)***, for review on July 19, 2017. However, we found the name, (b) (4)*** unacceptable under NDA 210136 and IND 114082 on August 25, 2017 due to orthographic similarities, phonetic similarities and shared product characteristics with the proprietary names, (b) (4)[c] Thus, Braeburn submitted the name, Brixadi, for review on November 21, 2017. We found the name, Brixadi, conditionally acceptable on January 10, 2018.[d] On January 19, 2018, NDA 210136 was issued a Complete Response (CR) letter due to clinical, statistical, nonclinical, product quality, device, microbiology and drug product deficiencies. On May 23, 2018, Braeburn submitted a response to address the deficiencies outlined in FDA's January 19, 2018 CR letter.

On June 22, 2018, the resubmission of NDA 210136 was deemed incomplete and an Acknowledge Incomplete Response Letter was issued to Braeburn.

On June 26, 2018, Braeburn submitted a Class 2 Resubmission to NDA 210136 to address the deficiencies identified in the June 22, 2018 Acknowledge Incomplete Response letter. We reviewed the proprietary name, Brixadi, and found the name conditionally acceptable on August 12, 2018.[e] On December 21, 2018, NDA 210136 received Tentative Approval under 21 CFR 314.105 with final approval subject to expiration of a period of patent protection and/or exclusivity.

On June 1, 2020, Braeburn submitted a Request for Final Approval for NDA 210136. However, on December 1, 2020, NDA 210136 received another CR due to a facility inspections deficiency.

---

[a] Shah, M. Proprietary Name Review for Brixadi*** (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 10. Panorama No. 2017-18773253.

[b] Shah, M. Proprietary Name Review for (b) (4)*** (IND 114082). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 MAR 31. Panorama No. 2016-10707590.

[c] Shah, M. Proprietary Name Review for (b) (4)*** (IND 114082 and NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 AUG 25. Panorama No. 2017-16036139 and 2017-16874573.

[d] Shah, M. Proprietary Name Review for Brixadi*** (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 10. Panorama No. 2017-18773253.

[e] Wilson, V. Proprietary Name Review for Brixadi (NDA 210136). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 AUG 13. Panorama No. 2018-23538531.

On June 15, 2021, Braeburn submitted a response to address the facility inspection deficiency as a class 2 resubmission. In the class 2 resubmission, Braeburn also re-submitted the name, Brixadi, for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 15, 2021.

- Intended Pronunciation: brix a' dee
- Active Ingredient: buprenorphine
- Indication of Use: treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine
- Route of Administration: subcutaneous
- Dosage Form: extended-release injection
- Strength: Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/ 0.64 mL Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL
- Dose and Frequency: Inject 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL or 32 mg/ 0.64 mL subcutaneously once weekly; Inject 64 mg/0.18 mL, 96 mg/0.27 mL or 128 mg/0.36 mL subcutaneously once monthly
- How Supplied: single dose, prefilled safety syringe
- Storage: USP Controlled Room Temperature

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Brixadi would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) and the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) concurred with the findings of OPDP's assessment for Brixadi.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On July 2, 2021, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) did not forward any comments or concerns relating to Brixadi at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred thirty-two (132) practitioners participated in DMEPA's prescription studies for Brixadi. We note that several participants in the verbal prescription study, interpreted the proposed name, Brixadi, as beginning with an 'R' sound as opposed to a 'B' sound. For example, participants interpreted the name as Rek-adi, Rexaddy, Rexadi, Rexady, Rickadee, Rixaddi, Rixaddy, Rixadi, and Rixady. However, the responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[g] identified 279 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 none of the product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 15 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**

[f] USAN stem search conducted on June 22, 2021.

[g] POCA search conducted on June 22, 2021 in version 4.4.

Highly similar name pair: combined match percentage score ≥70%	0
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	15
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 15 names contained in Table 1 determined none of the names will pose a risk for confusion with Brixadi as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA 1 communicated our findings to the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP). At that time we also requested additional information or concerns that could inform our review. On September 3, 2021, the Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) stated no additional concerns with the proposed proprietary name, Brixadi.

3 CONCLUSION

The proposed proprietary name, Brixadi, is acceptable.

If you have any questions or need clarifications, please contact Tamika White, OSE project manager, at 301-796- 0310.

3.1 COMMENTS TO BRAEBURN PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 15, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

2. Phonetic and Orthographic Computer Analysis (POCA)

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

Drugs@FDA

Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved *brand name* and *generic drugs*; *therapeutic biological products*, *prescription* and *over-the-counter* human drugs; and *discontinued drugs* (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

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

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

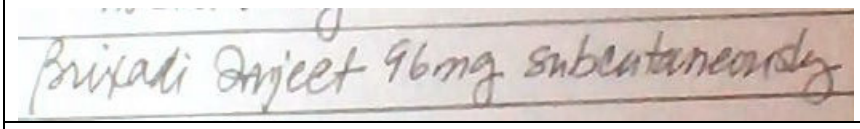
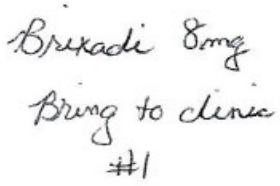
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Brixadi Study (Conducted on June 25, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  	Brixadi 8 mg Bring to clinic Dispense # 1
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Brixadi	

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Brixadi

265 People Received Study

132 People Responded

Study Name: Brixadi

Total	34	31	38	29	
INTERPRETATION	**OUTPATIENT**	**CPOE**	**VOICE**	**INPATIENT**	**TOTAL**
BREXATI	0	0	1	0	1
BRIXADDI	0	0	1	0	1
BRIXADDY	0	0	3	0	3
BRIXADI	34	31	7	22	94
BRIXADI INJECT	0	0	0	3	3
BRIXADI INJECTION	0	0	0	1	1
BRIXADI JAJEET	0	0	0	1	1
BRIXADY	0	0	3	0	3
BRIXALI	0	0	0	2	2
REK-ADI	0	0	1	0	1
REXADDY	0	0	1	0	1
REXADI	0	0	1	0	1
REXADY	0	0	1	0	1
RICKADEE	0	0	1	0	1
RIXADDI	0	0	5	0	5
RIXADDY	0	0	2	0	2
RIXADI	0	0	7	0	7
RIXADY	0	0	3	0	3
RIXADY 8 MG	0	0	1	0	1

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

No.	**Proposed name:** Brixadi **Established name:** buprenorphine **Dosage form:** extended-release injection **Strength(s):** Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/ 0.64 mL Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL **Usual Dose:** Inject 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL or 32 mg/ 0.64 mL subcutaneously once weekly; Inject 64 mg/0.18 mL, 96 mg/0.27 mL or 128 mg/0.36 mL subcutaneously once monthly	**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.**
	N/A		

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.	Brexafemme	60
2.	Brenzavvy***	60

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:** Brixadi **Established name:** buprenorphine **Dosage form:** extended-release injection **Strength(s):** Weekly: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, 32 mg/ 0.64 mL Monthly: 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL **Usual Dose:** Inject 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL or 32 mg/ 0.64 mL subcutaneously once weekly; Inject 64 mg/0.18 mL, 96 mg/0.27 mL or 128 mg/0.36 mL subcutaneously once monthly	**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.	Qbrexa	66	This name pair has sufficient orthographic and phonetic differences.
2.	Baloxavir	58	This name pair has sufficient orthographic and phonetic differences.
3.	Brukinsa	58	This name pair has sufficient orthographic and phonetic differences.
4.	(b) (4) ***	56	This name pair has sufficient orthographic and phonetic differences.
5.	Bryhali	56	This name pair has sufficient orthographic and phonetic differences.
	Breztri	55	This name pair has sufficient phonetic differences. The name Breztri can contain a downstroke “z” followed immediately by an upstroke cross lettered “t.” This can provide some orthographic differences in the infix compared to Brixadi. Furthermore, Breztri is the root name for the proprietary name Breztri Aerosphere. Therefore, the modifier, Aerosphere, if included on a prescription/medication order, would help to distinguish these names.

			Additionally, there are multiple differences in product characteristics that would minimize the potential for errors. Both products have differing dosage forms (injection vs inhalation aerosol). The routes of administration do not overlap (subcutaneous vs. oral inhalation). The dosages do not overlap (8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, or 32 mg/ 0.64 mL once weekly or 64 mg/0.18 mL, 96 mg/0.27 mL, or 128 mg/0.36 mL once monthly vs. 2 inhalations twice daily). Furthermore, Brixadi is subject to a risk evaluation and mitigation strategy (REMS) program that includes, among other elements, a restricted distribution program. The purpose of the restricted distribution program is to ensure that BRIXADI is only dispensed to and administered by a healthcare provider (HCP) for the treatment of moderate to severe opioid use disorder. Therefore, if a prescription or medication order for Brixadi is misinterpreted as Breztri and dispensed to the HCP, the administering HCP would likely confirm patient's history of opioid use disorder and previous administration date of Brixadi prior to administering to the patient, thus noticing that the incorrect product was dispensed. The BRIXADI REMS program also requires that both healthcare settings and pharmacies that order and dispense Brixadi are certified in the REMS program. Therefore, if a prescription or medication order for Breztri was misinterpreted for Brixadi in the outpatient setting, the dispensing pharmacist/technician would likely notice that a prescription should not be directly dispensed to a patient and call the prescribing physician to clarify the order.

			While we note that not all elements above may individually be included on a prescription or relied upon to mitigate medication errors, when all of the aforementioned mitigations are considered in totality, we find the risk of confusion is adequately minimized in this case. As such, we determined that Brixadi and Breztri Aerosphere can safely coexist on the market.

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

No.	Name	POCA Score (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	55	Proposed proprietary name withdrawn by the Applicant on August 6, 2020 under IND (b) (4) The IND was placed in inactive status on January 21, 2021.
2.	Coraxis	55	Veterinary product used as broad-spectrum protection against heartworm and intestinal parasite
3.	Suberic Acid	55	This is not a drug. This is a substance used in drug syntheses and plastic manufacturing.

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

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

No.	Name	POCA Score (%)
1.	Trikafta	57
2.	(b) (4)***	56
3.	Trijardy	56
4.	Drizalma	55

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/

CAMERON D CLARK
09/07/2021 07:28:25 AM

VALERIE S VAUGHAN
09/07/2021 08:03:23 AM

LUBNA A MERCHANT
09/07/2021 08:25:02 AM
Signed on behalf of Irene Chan

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	August 13, 2018
Application Type and Number:	NDA 210136
Product Name and Strength:	Brixadi (buprenorphine) injection, Weekly injection: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL Monthly injection: 64 mg/0.18 mL, 96 mg/0.27 mL, and 128 mg/0.36 mL
Total Product Strength:	Weekly: 50 mg/mL Monthly: 356 mg/mL
Product Type:	Single-ingredient Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Braeburn Pharmaceuticals, Inc
Panorama #:	2018-23538531
DMEPA Safety Evaluator:	Valerie S. Wilson, PharmD
DMEPA Team Leader:	Otto L. Townsend, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Brixadi, which was found conditionally acceptable under NDA 210136 on January 10, 2018.[a]

The application received a Complete Response letter on January 19, 2018.

The Applicant requested a review of the proposed proprietary name, Brixadi, on June 5, 2018. The initial Class 2 Resubmission of the application was received on May 23, 2018; however, it was deemed incomplete. Consequently, the complete resubmission was received on June 26, 2018.We note that there is a change (b) (4) All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. We also evaluated previously identified names taking into account the change in strength (removal of the 160 mg/0.45 mL strength) for Brixadi.

During our re-assessment, the proposed proprietary name, Brukinsa***, was identified which had not been previously evaluated. Our analysis of this name pair determined the proposed name Brukinsa*** can safely coexist with the proposed proprietary name Brixadi on the market. There are sufficient orthographic and phonetic differences between the name pair. Additionally, there is no overlap or numerical similarity in strength or dose between these products that may potentiate the risk for medication error.

Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The July 16, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on August 2, 2018. At that time, we also requested additional

[a] Shah, M. Proprietary Name Review for Brixadi NDA 210136. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 10. Panorama No. 2017-18773253.

information or concerns that could inform our review. Per e-mail correspondence from DAAAP on August 9, 2018, they stated no additional concerns with the proposed proprietary name, Brixadi.

3 CONCLUSIONS

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

If you have any questions or need clarifications, please contact Davis Matthew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on June 5, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**
   USAN Stems List contains all the recognized USAN stems.

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

/s/

VALERIE S WILSON
08/13/2018

OTTO L TOWNSEND
08/14/2018

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	January 10, 2018
Application Type and Number:	NDA 210136
Product Name and Strength:	Brixadi (buprenorphine) injection, 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL, (b) (4) (b) (4)
Product Type:	Single-ingredient combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Braeburn Pharmaceuticals, Inc.
Panorama #:	2017- 18773253
DMEPA Safety Evaluator:	Millie Shah, PharmD, BCPS
DMEPA Team Leader:	Otto L. Townsend, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Brixadi, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted (b) (4) for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, (b) (4)*** on October 11, 2016. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, (b) (4)*** acceptable in OSE Review #2016-10707590, dated March 31, 2017. The Applicant withdrew the request for review of the proprietary name (b) (4)*** on June 28, 2017. Thus, the Applicant submitted the name, (b) (4)***, for review on July 19, 2017. However, we found the name, (b) (4)*** unacceptable due to orthographic or phonetic similarities and shared product characteristics with the proprietary names, (b) (4) under NDA 210136 and IND 114082 on August 25, 2017.

Thus, the Applicant submitted the name, Brixadi, for review on November 9, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the November 9, 2017 proprietary name submission.

- Intended Pronunciation: brix a' dee
- Active Ingredient: buprenorphine
- Indication of Use: opioid addiction
- Route of Administration: subcutaneous
- Dosage Form: injection
- Strength: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4)
- Dose and Frequency: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL weekly or 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) monthly
- How Supplied: Each individual carton will contain one single use syringe that is prefilled with the appropriate volume
- Storage: room temperature (between (b) (4) – 25°C) in accordance with local and federal guidelines for the storage of Schedule III controlled substances.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the name.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE e-mail dated December 4, 2017, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred seven practitioners participated in DMEPA's prescription studies. 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 verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[b] identified 133 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Brixadi will be available in 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) (b) (4) strength(s). Because the 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL are not typical strengths that are commonly marketed, we

[a] USAN stem search conducted on November 15, 2017.

[b] POCA search conducted on November 20, 2017 in version 4.2.

searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	127
Low similarity name pair: combined match percentage score ≤54%	9

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

Our analysis of the 139 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on January 3, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DAAAP on January 9, 2018, they stated no additional concerns with the proposed proprietary name, Brixadi.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 9, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

APPEARS THIS WAY ON ORIGINAL

4 REFERENCES

1. ***USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)***

   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.

3. ***Electronic Drug Registration and Listing System (eDRLS) database***

The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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. [c]

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

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

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

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

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

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

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

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

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.

Three 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 or verbal pronunciation of the drug name. 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 orthographic or phonetic vulnerability of the proposed name to be misinterpreted by healthcare practitioners.

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

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

   The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name. The OND or OGD Regulatory Division is requested to provide any further information that might inform DMEPA's final decision on the proposed name.

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

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

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

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

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

Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		
Y/N	Do the suffixes of the names appear dissimilar when scripted?		

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

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

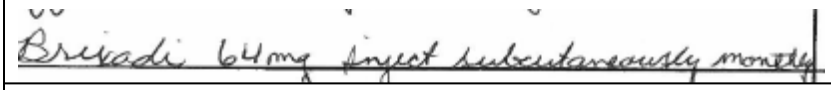
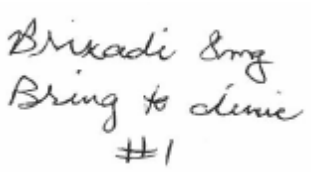
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Brixadi Study (Conducted on November 27, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Brixadi 8 mg Bring to clinic Dispense #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

295 People Received Study
107 People Responded

Study Name: Brixadi

Total	**35**	**30**	**42**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
BREIBADI	0	0	1	1
BREXEDY	0	1	0	1
BRICKSADEI 8MG	0	1	0	1
BRICSADI	0	1	0	1
BRIJCADI	0	0	1	1
BRISCADI	0	0	2	2
BRIXADE	0	0	1	1
BRIXADEE	0	2	0	2
BRIXADI	35	3	34	72
BRIXADY	0	4	0	4
BRIXEDI	0	2	0	2
BRIXIDE	0	1	0	1
BRIXIDEE	0	2	0	2
BRIXIDI	0	4	0	4
BRIXIDIE	0	1	0	1
BRIXIDY	0	2	0	2
BRIXITY	0	3	0	3
BRIXODI	0	0	1	1
BRIXODIE	0	1	0	1
BRIZEDE	0	1	0	1
BRUIVADI	0	0	1	1
BRUXADI	0	0	1	1
REXIDI	0	1	0	1

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

No.	**Proposed name: Brixadi Established name: buprenorphine Dosage form: injection Strength(s): 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) Usual Dose: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL weekly or 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) monthly**	**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.	Brixadi	100	Name subject of this review
2.	(b) (4)***	74	(b) (4)
3.	Brexidol	70	International product marketed in Norway and Sweden

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 (%)
4.	Abrilada***	68
5.	Boric Acid	68
6.	Purixan	68
7.	Drixomed	66

No.	Name	POCA Score (%)
8.	Rixubis	65
9.	Biaxin	64
10.	Bidex-DMI	64
11.	Braftovi***	64
12.	(b) (4)***	64
13.	Truxima***	64
14.	Trixaicin	63
15.	Brigatinib	62
16.	Crixivan	62
17.	Rifadin	62
18.	Arixtra	60
19.	Brovex ADT	60
20.	Bridion	59
21.	Brisdelle	59
22.	Bronkaid	59
23.	Baqsimi***	58
24.	Bidex-DM	58
25.	(b) (4)***	58
26.	Tri-Pseudo	58
27.	Aridex-D	57
28.	Baraclude	57
29.	B-Vex D	57
30.	Truxadryl	57
31.	Baridium	56
32.	Biktarvy***	56
33.	Brevital	56
34.	Brioschi	56
35.	Bronkids	56
36.	Nexobrid***	56
37.	Amrix	55
38.	Apixaban	55
39.	Brilinta	55
40.	(b) (4)***	55
41.	(b) (4)***	55
42.	(b) (4)***	47

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: Brixadi Established name: buprenorphine Dosage form: injection Strength(s): 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) Usual Dose: 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL weekly or 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL (b) (4) monthly	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
43.	Betrixaban	63	This name pair has sufficient orthographic and phonetic differences.
44.	Rinade-B.I.D.	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
45.	Brintellix	49
46.	Hexabrix	48
47.	Xtandi	48
48.	Bexsero	46
49.	Brexpiprazole	44
50.	Betoptic	36

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

No.	Name	POCA Score (%)	Failure preventions
51.	Brexidol	70	International product marketed in Norway and Sweden
52.	Brexin L.A.	68	Name identified in RxNorm. Unable to find product characteristics in commonly used drug databases
53.	Miraxid	68	International product marketed formerly in Austria and Switzerland.

No.	Name	POCA Score (%)	Failure preventions
54.	Brevidil	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	Broxil	66	International product marketed in the Netherlands
56.	Duraxin	66	International product formerly marketed in Puerto Rico
57.	Trexima	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
58.	(b) (4)***	64	Proposed proprietary name withdrawn by the Applicant. Product approved under new proprietary name, Bridion.
59.	Dixarit	64	International product marketed in several foreign countries
60.	Drixoral	64	Brand discontinued with no generic equivalent available. NDA 013483 withdrawn FR effective 11/3/2016.
61.	Truxade	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
62.	Bricanyl	62	Brand discontinued with no generic equivalent available. NDA 017466, 017618, and 018000 withdrawn FR effective 12/07/2007.
63.	Brovex D	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
64.	(b) (4)***	61	Proposed proprietary name for BLA 761042 found unacceptable by DMEPA (OSE# 2015-1210669 and 2015-1210671). BLA 761042 approved under new proprietary name Erelzi.
65.	Britiazim	61	International product formerly marketed in the United Kingdom
66.	Bidex-A	60	This name was identified in RxNorm. However, this product is listed as discontinued per the Redbook with no available generic equivalents.
67.	(b) (4)***	60	Proposed proprietary name for IND (b) (4) found acceptable (OSE # (b) (4)); however, IND status is terminated (b) (4)
68.	Brovex ADM	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
69.	Traxam	60	International product marketed in the United Kingdom

No.	Name	POCA Score (%)	Failure preventions
70.	Bepridil	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
71.	Brevidil M	58	International product formerly marketed in the United Kingdom
72.	Bristagen	57	Brand discontinued with no generic equivalent available. ANDA 062288 withdrawn FR effective 06/22/1999.
73.	Barstatin 100	56	Brand discontinued with no generic equivalent available. ANDA 062489 withdrawn FR effective 12/18/1992.
74.	Biavax Ii	56	Name identified in RxNorm database. Brand discontinued per Facts &Comparisons, Clinical Pharmacology, and Micromedex Redbook
75.	Brocadopa	56	International product formerly marketed in Germany
76.	Triad	56	Brand discontinued with no generic equivalent available. ANDA 089023 withdrawn FR effective 08/16/1999.
77.	Basic Red 51	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
78.	Pripsen	51	International product formerly marketed in the United Kingdom
79.	Radri	49	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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

No.	Name	POCA Score (%)
80.	Droxia	64
81.	Trioxin	63
82.	Daxbia	62
83.	Perox-Aid	62
84.	Praxbind	62

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

No.	Name	POCA Score (%)
85.	Tribaxin	62
86.	Draxxin	61
87.	Dristan	61
88.	Abraxane	60
89.	Aristada	60
90.	Droxicam	60
91.	Farxiga	60
92.	M-R-Vax Ii	60
93.	Primaxin	60
94.	Tripedia	59
95.	Adlyxin	58
96.	Chibroxin	58
97.	Dexair	58
98.	Droxidopa	58
99.	Glyxambi	58
100.	Peroxin A	58
101.	Peroxin A 10	58
102.	Rexista	58
103.	Rituxan	58
104.	Tresiba	58
105.	Triactin	58
106.	Ubretid	58
107.	Uric Acid	58
108.	Marax DF	57
109.	Nexavir	57
110.	Ridafed	57
111.	Trapidil	57
112.	Trux-Adryl	57
113.	Abciximab	56
114.	Dexatrim	56
115.	Dritail	56
116.	Flaxedil	56
117.	H-B-Vax Ii	56
118.	Prandin	56
119.	Prepidil	56
120.	Pri-Dextra	56
121.	Procardia	56
122.	Prolixin	56
123.	Ridifed	56
124.	Triafed	56
125.	Tri-Statin	56
126.	Troxyca	56
127.	Tryexta	56

No.	Name	POCA Score (%)
128.	Agaric Acid	55
129.	Doxidan	55
130.	Prevacid	55
131.	Prevacid***	55
132.	Priadel	55
133.	Primaxin IM	55
134.	Primaxin IV	55
135.	Rexulti	55
136.	Treximet	55
137.	Trikof D	55
138.	Triposed	55
139.	Viractin	55

Appendix I: Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences.

No.	Name
1.	Aesculus E Cort. 32 Special Order
2.	Aloe Soothing
3.	Amitiza
4.	Anascorp
5.	Anavip
6.	Antibacterial Hand Sanitizer
7.	Arrid Xx Roll On
8.	Aruba Aloe Deodorant Men
9.	Aruba Aloe Deodorant Women
10.	Atacand
11.	Babys Butt Aid
12.	Babys Butt Care Diaper Rash
13.	Balmers Hanryeoncho W
14.	Bisque Foundation Spf 20
15.	Boudreauxs
16.	Budesonide
17.	Budesonide Nasal
18.	Candesartan
19.	Candesartan Cilexetil
20.	Cellbn First Care Cleanser
21.	Childrens Rhinocort Allergy
22.	Chirhostim
23.	Cold And Hot
24.	Cold Buster
25.	Diaprex
26.	Dioscorea Batata 16 Special Order

No.	Name
27.	Dr Circu One
28.	Dr.G Revital Enhancer Cleansing Foam
29.	Easydew Daily Moist Cleansing Whip Foa M
30.	Emotional Balance
31.	Exalgo
32.	Fortify
33.	Foscavir
34.	Gabitril
35.	Galantamine
36.	Galantamine Hydrobromide
37.	Gillette Clear Arctic Ice
38.	Gillette Clear Cool Wave
39.	Gillette Clear Sport Triumph
40.	Gillette Clear Ultimate Fresh
41.	Gillette Clear Undefeated
42.	Gillette Clear Wild Rain
43.	Gillette Endurance Arctic Ice Clear
44.	Gillette Endurance Clear Brisa Tropical
45.	Gillette Endurance Cool Wave Clear
46.	Gillette Endurance Power Beads Cool Wave Clear
47.	Gillette Endurance Ultimate Fresh Clear
48.	Gillette Endurance Wild Rain Clear
49.	Gillette Sport Power Rush Clear
50.	Gillette Sport Triumph Clear
51.	Gillette Sport Undefeated Clear
52.	Gim
53.	Gold Bond Pain Relieving Foot
54.	Hydromorphone Hydrochloride
55.	Imada Four Seasons Safe Analgesic Balm
56.	Incontinence Care Wipe
57.	Inflammation OTC
58.	Kiehls Since 1851 Superbly Efficient Antiperspirant And Deodorant
59.	Ky
60.	Levothyroxine
61.	Medpak Derma Guard
62.	Medrol
63.	Methylprednisolone
64.	Mineral Wear Talc-Free Mineral Liquid Foundation
65.	Missha All Around Safe Block Waterproof Sun
66.	Missha Time Revolution Vitality Serum
67.	Mozobil
68.	Natural Sun Saving Face

No.	Name
69.	Neutrogena Healthy Skin Makeup
70.	Neutrogena Shine Control Makeup
71.	Norepinephrine Bitartrate
72.	Obeo 7way Moisture
73.	Old Spice High Endurance Clear
74.	Old Spice Red Zone Collection Swagger
75.	On Guard Sanitizing Mist
76.	Ondansetron
77.	Ondansetron Hydrochloride
78.	Ondansetron Hydrochloride And Dextrose
79.	Pcxx 1.64 Stannous Rns Mint
80.	Pcxx 1.64 Stannous Rnsstrawberry
81.	Perphenazine
82.	Plagentra Mothers Belly
83.	Portrazza
84.	Premierpro Flushable Wipes With Dimethicone
85.	Razadyne
86.	Rhinocort Allergy
87.	Rhinocort Aqua
88.	Ricetsotox
89.	Safeguard
90.	Salacyn
91.	Secret Active Cool Clear
92.	Secret Australia Eucalyptus Blossoms Clear
93.	Secret Bora Bora Fresh Orchid Clear
94.	Secret Capri Island Retreat Clear
95.	Secret Chill Ocean Clear
96.	Secret Classic Cocoa Butter Scent Clear
97.	Secret Cool Waterlily Clear
98.	Secret Fresh Orchid Clear
99.	Secret Hawaii Citrus Breeze Clear
100.	Secret Hawaii Citrus Clear
101.	Secret Luxe Lavender Clear
102.	Secret Outlast Active Fresh Clear
103.	Secret Outlast Clear Fresh Lotus
104.	Secret Outlast Clear Protecting
105.	Secret Paris Romantic Rose Clear
106.	Secret Paris Rose Clear
107.	Secret Pasion De Tango Clear
108.	Secret Scent Expressions Cabana Cool Clear
109.	Secret Scent Expressions Clear Coconut Splash
110.	Secret Scent Expressions Clear Ooh La Lavender
111.	Secret Scent Expressions Clear So Very Summerberry

No.	Name
112.	Secret Scent Expressions Sunny Citrus Clear
113.	Secret Scent Expressions Truth Or Pear Clear
114.	Secret Va Vanilla Clear
115.	Secret Wild Sugar Clear
116.	Serdaen
117.	Smilecare
118.	Stama Pro
119.	Sure Original Solid Fresh And Cool
120.	Sure Original Solid Fresh Scent
121.	Sure Original Solid Powder
122.	Sure Original Solid Regular
123.	Sure Original Solid Unscented
124.	Therabreath Toothpaste
125.	Tomatox Magic Massage Pack
126.	True Natural Broad Spectrum Spf 50
127.	Tuberculinum Koch
128.	Ultra-Technekow
129.	Vanilla Silq MD
130.	Walgreens Original
131.	Yeast Ultra Deep Cleansing Whip Foam

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MILLIE C BRAHMBHATT
01/10/2018

OTTO L TOWNSEND
01/10/2018

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	August 25, 2017
Application Type and Number:	NDA 210136 and IND 114082
Product Name and Strength:	(b) (4) (buprenorphine) injection, 8 mg/0.16 mL, 16 mg/0.32 mL, 24 mg/0.48 mL, and 32 mg/0.64 mL, 64 mg/0.18 mL, 96 mg/0.27 mL, 128 mg/0.36 mL, (b) (4)
Product Type:	Single-ingredient combination product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Braeburn Pharmaceuticals, Inc.
Panorama #:	2017-16036139; 2017- 16874573
DMEPA Primary Reviewer:	Millie Shah, PharmD, BCPS
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Director:	Irene Chan, PharmD, BCPS
DMEPA Director:	Todd Bridges, RPh

26 Pages have been Withheld in Full as B4 (CCI/TS) immediately following this page

---

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

MILLIE C BRAHMBHATT
08/25/2017

OTTO L TOWNSEND
08/25/2017

TODD D BRIDGES on behalf of IRENE Z CHAN
08/31/2017

TODD D BRIDGES
08/31/2017