# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 205836Orig1s000
# 205837Orig1s000
# 205838Orig1s000

# PROPRIETARY NAME REVIEW(S)

**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:** | February 21, 2015 |
| **Application Type and Number:** | NDAs 205836, 205838, 205837 |
| **Product Name and Strength:** | Briviact (brivaracetam)<br>Tablets 10 mg, 25 mg, 50 mg, 75 mg and 100 mg<br>Oral Solution 10 mg/mL<br>Intravenous injection 50 mg/5 mL |
| **Product Type:** | Single Product |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | UCB, Inc. |
| **Panorama #:** | 2014-45369, 2014-45371, 2014-45370 |
| **DMEPA Primary Reviewer:** | Justine Harris, RPh |
| **DEMPA Team Leader:** | Danielle Harris, PharmD, BCPS |
| **DMEPA Associate Director:** | Irene Z. Chan, PharmD, BCPS |

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Briviact, 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 did not submit an external name study.

## 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Briviact on April 19, 2012 for INDs 070205, (b) (4), 103908, and 110606. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Briviact conditionally acceptable in OSE Review # 2012-963, dated October 11, 2012.

The Applicant submitted the name, Briviact, for review under the NDAs on November 19, 2014. The product characteristics have not changed, (b) (4) available as a 10 mg/mL oral solution only.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the November 19, 2014 proprietary name submission.

- Intended Pronunciation: briv-ee-akt
- Active Ingredient: brivaracetam
- Indication of Use: Adjunctive therapy in the treatment of partial onset seizures in patients 16 years of age and older with epilepsy
- Route of Administration: oral and intravenous
- Dosage Form: tablets, oral solution and injection
- Strength: Tablets: 10 mg, 25 mg, 50 mg, 75 mg and 100 mg tablets;

  Oral Solution: 10 mg/mL

  Intravenous injection: 50 mg/5mL vial

- Dose and Frequency: Starting dose 50 mg twice daily. Based on individual patient response, the dose may be adjusted between 25 mg twice daily and 100 mg twice daily. Not recommended in end-stage renal disease patients undergoing dialysis; reduce dose in patients with hepatic impairment. When discontinuing, reduce dosage gradually to minimize the risk of increased seizure frequency and status epilepticus; for intravenous injection: Can be administered intravenously without further dilution or may be mixed with diluents and other compounds as listed in the PI; dosage is the same as oral
- How Supplied: Bottles of 60 tablets; oral solution 300 mL amber glass bottles; injection supplied as single- use 5 mL vial

- Storage: Store at 25°C [77°F]; excursions are permitted to 15°C to 30°C [59°F to 86°F]

# 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. DMEPA and the Division of Neurology Products (DNP) 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[1].

### *2.2.2 Components of the Proposed Proprietary Name*

The Applicant did not provide a derivation or intended meaning for the proposed name, Briviact 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.

We note the Applicant's use of the same name for three different dosage forms (oral tablet, oral liquid and injection). The proposed dosing does not differ between the various dosage forms, which minimizes the risk for improper dose errors if the wrong dosage form is inadvertently dispensed or administered. While there is a risk for a patient receiving the wrong dosage form for a product, we believe that this can be appropriately mitigated through labels and labeling. Additionally, the convention of using the same proprietary name for different dosage forms of a drug has been utilized in the marketplace and we do not have any concerns with at this time.

### *2.2.3 FDA Name Simulation Studies*

Two hundred and eighty 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.

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[1]USAN stem search conducted on January 6, 2015.

### *2.2.4 Comments from Other Review Disciplines at Initial Review*

In response to the OSE, December 24, 2014 e-mail, the Division of Neurology Products (DNP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

### *2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified from the FDA prescription simulation.

| **Table 1. POCA Search Results** | **Number of Names** |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 3 |
| Moderately similar name pair:<br>combined match percentage score ≥50% to ≤ 69% | 151 |
| Low similarity name pair:<br>combined match percentage score ≤49% | 0 |

### *2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength*

The proposed product, Briviact will be available in strength of 75 mg. Since this is not a commonly marketed strength, we searched the Pragmatic® Regulated Product Labeling Listing and Registration System (PR°PLLR™) database to identify any names with potential orthographic, spelling, and phonetic similarities with Briviact that were not identified in POCA, and found to have an overlap in strength with Briviact. The search results identified no names with orthographic or phonetic similarities.

| **Table 1A.** (PR°PLLR™) **Search Results** | **POCA score** |
|---|---|
| N/A | |

[2] POCA search conducted on January 6, 2015.

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

Our analysis of the 154 names contained in Table 1 determined none of the names pose a risk for confusion as described in Appendices C through H.

### *2.2.8 Communication of DMEPA's Analysis at Midpoint of Review*

DMEPA communicated our findings to the Division of Neurology Products (DNP) via e-mail on January 29, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Neurology Products (DNP) on February 10, 2015, they stated no additional concerns with the proposed proprietary name, Briviact.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Ermias Zerislassie, OSE project manager, at 301-796- 0097.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your November 19, 2014 submission 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.

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 DNCE. OPDP or DNCE 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 DNCE 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. [3]

[3] 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 medical and/or coined abbreviations in the proprietary name?** |
| | Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning. |
| **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 50% 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 ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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 with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it 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, etc.) may be limited when the strength or dose overlaps. We review 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 do not share a common strength or dose. | | | |
|---|---|---|---|
| Orthographic Checklist | | Phonetic Checklist | |
| **Y/N** | Do the names begin with different first letters?<br>*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?<br><br>**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 ≥50% 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.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>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.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>o 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.<br><br>o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity.<br><br>o 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)<br>• Do the names begin with different first letters?<br><br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br><br>• Are the lengths of the names dissimilar* when scripted?<br><br>*FDA considers the length of names different if the names differ by two or more letters.<br><br>• 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?<br><br>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br><br>• Do the infixes of the name appear dissimilar when scripted?<br><br>• Do the suffixes of the names appear dissimilar when scripted? | Phonetic Checklist (Y/N to each question)<br>• Do the names have different number of syllables?<br><br>• Do the names have different syllabic stresses?<br><br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br><br>• Across a range of dialects, are the names consistently pronounced differently? |

**Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).**

| |
|---|
| In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA 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. Briviact Oral Solution Study (Conducted on December 29, 2014)**

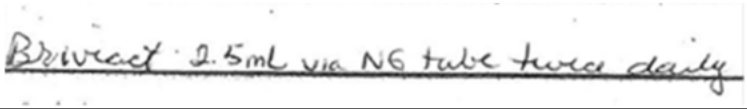
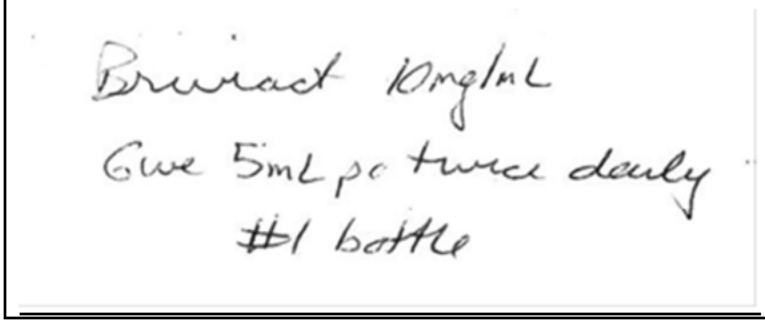
| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br> | Briviact 10 mg/mL<br>Give 5 mL po twice daily<br>Disp # 1 bottle |
| Outpatient Prescription:<br>  <br> | |

**Figure 2. Briviact Injection Study (Conducted on January 5, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| **Medication Order:**<br>Briviact 100mg IV BID<br>**Outpatient Prescription:**<br>Briviact 50mg/5mL<br>Bring to Clinic<br>#2 | **Briviact 50 mg/5mL injection**<br>**Disp # 2**<br>**Bring to clinic** |

**Figure 3. Briviact Oral Tablets Study (Conducted on January 9, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>Briviact 25mg twice daily<br>Outpatient Prescription:<br>Briviact 50mg<br>1 BID<br># 60 | Briviact 50 mg<br>One tablet twice daily<br>Disp # 60 |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Briviact oral solution conducted December 29, 2014**

252 People Received Study
99 People Responded

Study Name: Briviact

| Total | 35 | 29 | 35 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| ABRIVIAC | 0 | 1 | 0 | 1 |
| BERVIAC | 0 | 1 | 0 | 1 |
| BREURACT 10MG/ML | 1 | 0 | 0 | 1 |
| BREVIAC | 0 | 7 | 0 | 7 |
| BREVIACT | 14 | 1 | 0 | 15 |
| BREVIAT | 0 | 4 | 0 | 4 |
| BRIVAC | 0 | 1 | 0 | 1 |
| BRIVACET | 0 | 0 | 1 | 1 |
| BRIVACT | 0 | 0 | 5 | 5 |
| BRIVEICET | 0 | 0 | 1 | 1 |
| BRIVIAC | 0 | 1 | 0 | 1 |
| BRIVIACT | 10 | 8 | 26 | 44 |
| BRIVIAK | 0 | 2 | 0 | 2 |
| BRIVIAT | 0 | 3 | 0 | 3 |
| BRIVICET | 0 | 0 | 1 | 1 |
| BRIVOCT | 0 | 0 | 1 | 1 |
| BRUIACT | 1 | 0 | 0 | 1 |
| BRUIRACT | 1 | 0 | 0 | 1 |
| BRURIACT | 1 | 0 | 0 | 1 |
| BRUVIACT | 6 | 0 | 0 | 6 |
| ILLEGIBLE | 1 | 0 | 0 | 1 |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Briviact injection conducted January 5, 2015**

252 People Received Study
104 People Responded

Study Name: Briviact

| Total | 36 | 34 | 34 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| BARIACT | 0 | 0 | 1 | 1 |
| BEREVAC | 0 | 1 | 0 | 1 |
| BERVIACT | 0 | 2 | 0 | 2 |
| BIVIACT | 0 | 0 | 1 | 1 |
| BRAVIACT | 0 | 0 | 1 | 1 |
| BREVIA | 0 | 1 | 0 | 1 |
| BREVIAC | 0 | 2 | 0 | 2 |
| BREVIACT | 0 | 15 | 2 | 17 |
| BREVIAT | 0 | 1 | 0 | 1 |
| BRIVACT | 1 | 0 | 1 | 2 |
| BRIVIACT | 31 | 4 | 27 | 62 |
| BRIVIATT | 0 | 1 | 0 | 1 |
| BRIVICAT | 1 | 0 | 0 | 1 |
| BRIVICET | 1 | 0 | 0 | 1 |
| BRIVINET | 1 | 0 | 0 | 1 |
| BRIVIOCT | 1 | 0 | 0 | 1 |
| BRUVIACT | 0 | 1 | 0 | 1 |
| BRVIACT | 0 | 0 | 1 | 1 |
| BRYVIACT | 0 | 1 | 0 | 1 |
| PURVIAK | 0 | 1 | 0 | 1 |
| REVIACT 50MG/5ML INJ | 0 | 1 | 0 | 1 |
| RIVIACT | 0 | 2 | 0 | 2 |
| VEDIAC | 0 | 1 | 0 | 1 |

**FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)**

**Briviact oral tablets conducted January 9, 2015**

253 People Received Study
77 People Responded

Study Name: Briviact

| Total | 23 | 22 | 32 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| BREDIACT | 0 | 1 | 0 | 1 |
| BREVIACT | 0 | 0 | 1 | 1 |
| BREVIAT | 0 | 1 | 0 | 1 |
| BRIDIACK | 0 | 1 | 0 | 1 |
| BRIDIACT | 0 | 3 | 0 | 3 |
| BRIMIACT | 0 | 0 | 1 | 1 |
| BRINIACT | 0 | 1 | 0 | 1 |
| BRITIA | 0 | 1 | 0 | 1 |
| BRITIACT | 0 | 1 | 0 | 1 |
| BRIVIACT | 20 | 13 | 27 | 60 |
| BRIVIOCT | 0 | 0 | 1 | 1 |
| BRIVLACT | 3 | 0 | 0 | 3 |
| BRUVIACT | 0 | 0 | 2 | 2 |

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

| No. | **Proposed name: Briviact**<br>**Strength(s):** 10 mg, 25 mg, 50 mg, 75 mg and 100 mg tablets; 10 mg/mL oral solution and 50 mg/5mL vial<br>**Usual Dose**: Starting dose 50 mg twice daily. Based on patient response, the dose may be adjusted between 25 mg twice daily and 100 mg twice daily. | POCA Score (%) | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Briviact | 100 | Subject of this review |
| 2. | Bravecto | 74 | Veterinary product |
| 3. | Brovex CT | 70 | Discontinued product and no generics available |

**Appendix D:** Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Brevicon | 68 |
| 2. | Corifact | 64 |
| 3. | Breezee Mist | 61 |
| 4. | Brilinta | 60 |
| 5. | (b) (4) *** | 60 |
| 6. | Bionect | 56 |
| 7. | Brovana | 56 |
| 8. | Duetact | 56 |
| 9. | Iprivask | 55 |
| 10. | Brevoxyl | 54 |
| 11. | Triacet | 54 |
| 12. | Triacort | 54 |
| 13. | Trivase | 54 |
| 14. | Blistex | 52 |

| | | |
|---|---|---|
| 15. | (b) (4) *** | 52 |
| 16. | bromfenac | 52 |
| 17. | Quninact | 52 |
| 18. | Brevicon 28-day | 51 |
| 19. | Trezix | 51 |
| 20. | Brioschi | 50 |
| 21. | Periactin | 50 |
| 22. | Privine | 50 |
| 23. | Triacting | 50 |
| 24. | Brontex | 53 |
| 25. | Ravicti | 60 |

**Appendix E:** Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

| No. | **Proposed name: Briviact**<br>**Strength(s): 10 mg, 25 mg, 50 mg, 75 mg and 100 mg tablets; 10 mg/mL oral solution and 50 mg/5mL vial**<br>**Usual Dose: : Starting dose 50 mg twice daily. Based on patient response, the dose may be adjusted between 25 mg twice daily and 100 mg twice daily.** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | Bilivist | 67 | The infixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |
| 2. | Brevital | 62 | The suffixes of this name pair have sufficient orthographic differences<br>The third syllables of this name pair sound different |
| 3. | Brevibloc | 60 | The suffixes of this name pair have sufficient orthographic differences<br>The third syllables of this name pair sound different |
| 4. | Bridion*** | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences<br>The second and third syllables of this name pair sound different |
| 5. | Doribax | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |
| 6. | (b) (4)*** | 56 | The infixes of this name pair have sufficient orthographic differences<br>The first syllables of this name pair sound different |
| 7. | Grisactin | 56 | The suffixes of this name pair have sufficient orthographic differences |

| | | | |
|---|---|---|---|
| | | | The first and third syllables of this name pair sound different |
| 8. | Promacta | 56 | The suffixes of this name pair have sufficient orthographic differences<br>The first, second, and third syllables of this name pair sound different |
| 9. | beractant | 54 | The infixes of this name pair have sufficient orthographic differences<br>The second and third syllables of this name pair sound different |
| 10. | Benzacot | 53 | The infixes of this name pair have sufficient orthographic differences<br>The first and second syllables of this name pair sound different |
| 11. | Berinert | 52 | The suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |
| 12. | Bivigam | 52 | The suffixes of this name pair have sufficient orthographic differences<br>The third syllables of this name pair sound different |
| 13. | Brintellix | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences<br>The second syllables of this name pair sound different |
| 14. | Benicar HCT | 50 | The suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |
| 15. | (b) (4) *** | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |
| 16. | Varivax | 59 | The prefixes and suffixes of this name pair have sufficient orthographic differences<br>The first and third syllables of this name pair sound different |

**Appendix F:** Low Similarity Names (e.g., combined POCA score is ≤49%)

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | N/A | |

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

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 1. | Britaject | 66 | International product marketed in Cz and Norway |
| 2. | Brom-A-Cot | 66 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 3. | Brovex ADT | 66 | Formerly marketed in the US; no generic products available |
| 4. | Brovex | 65 | Formerly marketed in the US; no generic products available |
| 5. | Dryvax | 64 | Formerly marketed product (small pox vaccine) |
| 6. | Brovex D | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 7. | Brovex CB | 60 | Formerly marketed in the US; no generic products available |
| 8. | Brovex HC | 60 | Per Redbook database, |

| | | | |
|---|---|---|---|
| | | | product deactivated and no generics available |
| 9. | Brovex SR | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 10. | Uritact | 59 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 11. | Bromax | 58 | International product marketed in Portugal |
| 12. | Previcox | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 13. | Brevidil | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 14. | Britiazim | 56 | International product formerly marketed in UK |
| 15. | Broncot | 56 | International product marketed in Chile |
| 16. | Duract | 56 | Per Redbook database, product deactivated and no generics available. |
| 17. | Suprefact | 56 | International product marketed in numerous foreign countries |
| 18. | Borofax | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 19. | (b) (4) *** | 54 | Name withdrawn by the Applicant and the product |

| | | | |
|---|---|---|---|
| | | | was approved under proprietary name Bridion OSE # 2014-40699 |
| 20. | Brovex DM | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 21. | Brovex PB | 54 | Formerly marketed in the US; no generic products available |
| 22. | Brovex PB C | 54 | Formerly marketed in the US; no generic products available |
| 23. | Brovex PBC | 54 | Formerly marketed in the US; no generic products available |
| 24. | Brovex PD | 54 | Formerly marketed in the US; no generic products available |
| 25. | Perifix | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 26. | Refacto | 54 | Per Redbook database, product deactivated and no generics available |
| 27. | Triactin | 54 | Per Redbook database, product deactivated and no generics available |
| 28. | Bromatapp | 53 | Per Redbook database, product deactivated and no generics available |
| 29. | Bromates | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug.databases |
| 30. | Brovex ADM | 53 | Name identified in RxNorm database. Unable to find |

| | | | |
|---|---|---|---|
| | | | product characteristics in commonly used drug databases. |
| 31. | (b) (4) *** | 53 | This is the secondary proposed proprietary name and product approved under name Gadavist OSE # 2011-406 |
| 32. | Bidhist | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 33. | Brevidil M | 52 | International product formerly marketed in UK |
| 34. | Brivudine | 52 | Name identified in RxNorm database.Unable to find product characteristics in commonly used drug databases. |
| 35. | Broflex | 52 | International product formerly marketed in UK and India |
| 36. | Bronitin | 52 | Per Redbook database, product deactivated and no generics available |
| 37. | Burinex | 52 | International product marketed in numerous foreign countries |
| 38. | Brevicon 21-day | 51 | Discontinued per Drugs @ FDA ; no generics available |
| 39. | Bromatan | 51 | Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases |
| 40. | B-12 resin | 50 | Name identified in RxNorm database Unable to find product characteristics in commonly used drug databases |

| | | | |
|---|---|---|---|
| 41. | (b) (4)*** | 50 | Proposed proprietary name found unacceptable by DMEPA. Name withdrawn by the Applicant |
| 42. | (b) (4)*** | 50 | Name identified in names entered by SE database. Unable to find product characteristics in internal database |
| 43. | (b) (4)*** | 50 | This is a secondary proposed proprietary name and the product was approved under proprietary name Evekeo***2013-2461 |
| 44. | (b) (4)*** | 50 | Proposed Proprietary Name found unacceptable by DMEPA (OSE# 2012-2846). Product approved under new proprietary name Fetzima*** |
| 45. | Poly Pact | 50 | 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 notable spelling, orthographic and phonetic differences.

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Atrovent | 52 |
| 2. | Cartia XT | 50 |
| 3. | Darvocet | 51 |
| 4. | Diltia XT | 56 |
| 5. | Diovan HCT | 52 |
| 6. | Dramoject | 52 |
| 7. | Drihist | 60 |
| 8. | Drymax | 54 |

| | | |
|---|---|---|
| 9. | Durabac | 50 |
| 10. | Dura-Gest | 50 |
| 11. | Duranest | 50 |
| 12. | Duratest | 50 |
| 13. | Duravent | 60 |
| 14. | Dura-Vent | 60 |
| 15. | Dura-VentA | 50 |
| 16. | Evict | 52 |
| 17. | Freeze It | 50 |
| 18. | KBrovet | 60 |
| 19. | Mapravant | 50 |
| 20. | Pavacot | 56 |
| 21. | Praluent | 50 |
| 22. | Predacort 50 | 52 |
| 23. | Predaject-50 | 54 |
| 24. | Predicort-50 | 50 |
| 25. | Pred-Ject-50 | 54 |
| 26. | Prednicot | 51 |
| 27. | Prefest | 50 |
| 28. | Prevacid | 56 |
| 29. | Prevalite | 50 |
| 30. | Prevantics | 50 |
| 31. | Preven EC | 54 |
| 32. | Prevident | 59 |
| 33. | Prevpac | 56 |
| 34. | Prezista | 52 |
| 35. | Prialt | 50 |
| 36. | Pro-Fast | 56 |
| 37. | Promacet | 51 |
| 38. | Promacot | 56 |
| 39. | Propacet | 51 |

| | | |
|---|---|---|
| 40. | Propacet 100 | 51 |
| 41. | Pro-Vent | 57 |
| 42. | Provisc | 59 |
| 43. | Rapi-Ject | 53 |
| 44. | Renovist | 52 |
| 45. | Rybix | 50 |
| 46. | Rydapt | 50 |
| 47. | Serevent | 52 |
| 48. | Tranilast | 54 |
| 49. | Travatant | 51 |
| 50. | Tri Vent DM | 50 |
| 51. | Tri Vent HC | 50 |
| 52. | Triamcot | 51 |
| 53. | Triatex | 50 |
| 54. | Triferic | 52 |
| 55. | Trilocot | 52 |
| 56. | Tripohist | 50 |
| 57. | Trusopt | 50 |
| 58. | Ultravist | 53 |
| 59. | Ultravist 150 | 53 |
| 60. | Ultravist 240 | 53 |
| 61. | Ultravist 300 | 53 |
| 62. | Ultravist 370 | 53 |
| 63. | Viracept | 55 |
| 64. | Viravan-T | 57 |
| 65. | Vivactil | 55 |

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/s/

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02/21/2015

IRENE Z CHAN
02/22/2015