# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 214679Orig1s000

# 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:** | July 23, 2021 |
| **Application Type and Number:** | NDA 214679 |
| **Product Name and Strength:** | Eprontia (topiramate) solution, 25 mg/mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Azurity Pharmaceuticals, Inc. (Azurity) |
| **PNR ID #:** | 2021-1044723939 |
| **DMEPA Safety Evaluator:** | Chad Morris, PharmD, MPH |
| **DMEPA Acting Team Leader:** | Celeste Karpow, PharmD, MPH |
| **DMEPA Deputy Director:** | Danielle Harris, PharmD |

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# 1 INTRODUCTION

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

## 1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 26, 2021.

- Intended Pronunciation: ee-pron-tee-ah
- Active Ingredient: topiramate
- Indication of Use:
    - Epilepsy
        - Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older
        - Adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older.
    - Preventive treatment of migraine in patients 12 years of age and older.
- Route of Administration: oral
- Dosage Form: solution
- Strength: 25 mg/mL
- Dose and Frequency:

Dosing in Monotherapy Epilepsy:

Adults and Pediatric Patients 10 Years of Age and Older: The recommended dose for Topiramate Oral Solution monotherapy in adults and pediatric patients 10 years of age and older is 400 mg/day in two divided doses. The dose should be achieved by titration according to the following schedule (Table 1):

**Table 1: Monotherapy Titration Schedule for Adults and Pediatric Patients 10 years and older**

| | Morning Dose | Evening Dose |
|---|---|---|
| Week 1 | 25 mg | 25 mg |
| Week 2 | 50 mg | 50 mg |
| Week 3 | 75 mg | 75 mg |
| Week 4 | 100 mg | 100 mg |
| Week 5 | 150 mg | 150 mg |
| Week 6 | 200 mg | 200 mg |

Pediatric Patients 2 to 9 Years of Age: Dosing in patients 2 to 9 years of age is based on weight. During the titration period, the initial dose of Topiramate Oral Solution (ANDA) is 25 mg/day nightly for the first week. Based upon tolerability, the dosage can be increased to

50 mg/day (25 mg twice daily) in the second week. Dosage can be increased by 25-50 mg/day each subsequent week as tolerated. Titration to the minimum maintenance dose should be attempted over 5-7 weeks of the total titration period. Based upon tolerability and clinical response, additional titration to a higher dose (up to the maximum maintenance dose) can be attempted at 25-50 mg/day weekly increments. The total daily dose should not exceed the maximum maintenance dose for each range of body weight (Table 2).

**Table 2: Monotherapy Target Total Daily Maintenance Dosing for Patients 2 to 9 Years of Age**

| Weight (kg) | Total Daily Dose (mg/day)* Minimum Maintenance Dose | Total Daily Dose (mg/day)* Maximum Maintenance Dose |
|---|---|---|
| Up to 11 | 150 | 250 |
| 12 - 22 | 200 | 300 |
| 23 - 31 | 200 | 350 |
| 32 - 38 | 250 | 350 |
| Greater than 38 | 250 | 400 |

* Administered in two equally divided doses

Dosing in Adjunctive Therapy Epilepsy:

Adults (17 Years of Age and Older):

The recommended total daily dose of Topiramate Oral Solution as adjunctive therapy in adults with partial onset seizures or Lennox-Gastaut Syndrome is 200 to 400 mg/day in two divided doses, and 400 mg/day in two divided doses as adjunctive treatment in adults with primary generalized tonic-clonic seizures. Topiramate Oral Solution should be initiated at 25 to 50 mg/day, followed by titration to an effective dose in increments of 25 to 50 mg/day every week. Titrating in increments of 25 mg/day every week may delay the time to reach an effective dose. Doses above 400 mg/day have not been shown to improve responses in adults with partial-onset seizures.

Pediatric Patients 2 to 16 Years of Age:

The recommended total daily dose of Topiramate Oral Solution as adjunctive therapy for pediatric patients 2 to 16 years of age with partial-onset seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome is approximately 5 to 9 mg/kg/day in two divided doses. Titration should begin at 25 mg/day (or less, based on a range of 1 to 3 mg/kg/day) nightly for the first week. The dosage should then be increased at 1- or 2-week intervals by increments of 1 to 3 mg/kg/day (administered in two divided doses), to achieve optimal clinical response. Dose titration should be guided by clinical outcome. The total daily dose should not exceed 400 mg/day.

Dosing for the Preventive Treatment of Migraine:

The recommended total daily dose of Topiramate Oral Solution as treatment for patients 12 years of age and older for the preventive treatment of migraine is 100 mg/day administered in two divided doses

(Table 3). The recommended titration rate for Topiramate Oral Solution for the preventive treatment of migraine is as follows:

**Table 3: Preventive Treatment of Migraine Titration Schedule for Patients 12 Years of Age and Older**

| | Morning Dose | Evening Dose |
|---|---|---|
| Week 1 | None | 25 mg |
| Week 2 | 25 mg | 25 mg |
| Week 3 | 25 mg | 50 mg |
| Week 4 | 50 mg | 50 mg |

Dose and titration rate should be guided by clinical outcome. If required, longer intervals between dose adjustments can be used.

Dosing in Patients with Renal Impairment:

In patients with renal impairment (creatinine clearance less than 70 mL/min/1.73 m2), one-half of the usual adult dose of Topiramate Oral Solution is recommended.

Dosing in Patients Undergoing Hemodialysis:

To avoid rapid drops in topiramate plasma concentration during hemodialysis, a supplemental dose of Topiramate Oral Solution may be required. The actual adjustment should take into account 1) the duration of dialysis period, 2) the clearance rate of the dialysis system being used, and 3) the effective renal clearance of topiramate in the patient being dialyzed.

- How Supplied: 473 mL HDPE bottle
- Storage: 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59° to 86°F) [see USP Controlled Room Temperature]
- Reference Listed Drug/Reference Product: Topamax 25 mg capsule, NDA 020844

## 2 RESULTS

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

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Eprontia would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Neurology 2 (DN 2) concurred with the findings of OPDP's assessment for Eprontia.

### 2.2 SAFETY ASSESSMENT

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

### *2.2.1 United States Adopted Names (USAN) Search*

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

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

Azurity did not provide a derivation or intended meaning for the proposed proprietary name, Eprontia, in their submission. This proprietary name is comprised of a single word. We note the proposed name contains the letter strings "pr" and "tia", which are commonly used medical abbreviations meaning "per rectum" and "transient ischemic attack" that may be used on a prescription or medication order. Although we typically discourage the inclusion of medical abbreviations within proprietary names, we determined the location of the abbreviations "pr" and "tia" within the name is unlikely to be separated from the surrounding letters in a manner that would lead to confusion or result in wrong route of administration errors in this case. Other than the abbreviations "pr" and "tia", the proposed name, Eprontia, does not contain any components (i.e., a modifier, dosage form, etc.) that are misleading or can contribute to medication errors.

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

On May 17, 2021, the Division of Neurology 2 (DN 2) did not forward any comments or concerns relating to Eprontia at the initial phase of the review.

### *2.2.4 FDA Name Simulation Studies*

One hundred thirty-six practitioners participated in DMEPA's prescription studies for Eprontia.

One CPOE participant erroneously chose the deactivated product, Empro, from a "Dynamic Begins" picklist. Empro is a deactivated phenylpropanolamine (75 mg extended release capsule) product and does not have any generic equivalents (See Appendix G). We note the participant typed "empr" instead of "epr"; therefore, the correct selection, Eprontia, was not displayed within the picklist. Since Eprontia was not displayed, it appears the participant attempted to select an answer that was closest to the response needed given the goal of the simulated study. Based on these factors, we determined the risk for a medication error between this name pair is adequately minimized.

Appendix B contains the results from the prescription simulation studies.

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

Our POCA search[b] identified 330 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.

[a] USAN stem search conducted on May 12, 2021.

[b] POCA search conducted on May 12, 2021 in version 4.4.

### *2.2.6 Names Retrieved for Review Organized by Name Pair Similarity*

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

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

| Similarity Category | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 4 |
| Moderately similar name pair:<br>combined match percentage score ≥55% to ≤ 69% | 276 |
| Low similarity name pair:<br>combined match percentage score ≤54% | 52 |

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

Our analysis of the 332 names contained in Table 1 determined none of the names will pose a risk for confusion with Eprontia 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 2 (DN 2). At that time, we also requested additional information or concerns that could inform our review. On July 23, 2021, the Division of Neurology 2 (DN 2) stated no additional concerns with the proposed proprietary name, Eprontia.

## 3 CONCLUSION

The proposed proprietary name, Eprontia, is acceptable.

If you have any questions or need clarifications, please contact Casmir Ogbonna, OSE project manager, at 301-796-5272.

### 3.1 COMMENTS TO AZURITY PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 26, 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. [c]

[c] 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[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., 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

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

a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

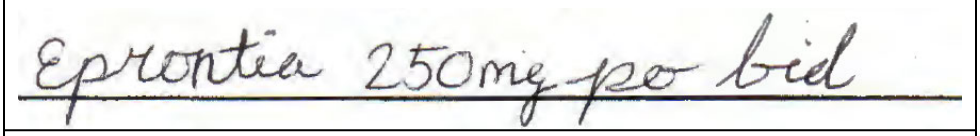
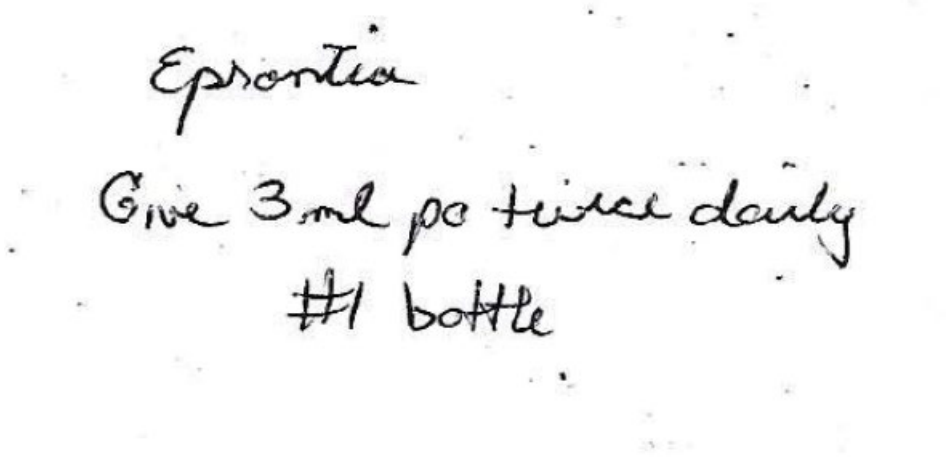
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when scripted?<br>*FDA considers the length of names different if the names differ by two or more letters.<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>• Is there different number or placement of cross-stroke or dotted letters present in the names?<br>• Do the infixes of the name appear dissimilar when scripted?<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>• Do the names have different syllabic stresses?<br>• Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?<br>• 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. Eprontia Study (Conducted on May 21, 2021)**

| **Handwritten Medication Order/Prescription** | **Verbal Prescription** |
|---|---|
| Medication Order:<br>  <br> | Eprontia<br>Give 3 mL by mouth twice daily<br>#1 bottle |
| Outpatient Prescription:<br>  <br> | |
| **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** | |
| Eprontia | |

**FDA Prescription Simulation Responses (Aggregate Report)**

**Study Name: Eprontia**
As of Date 6/24/2021

256 People Received Study
136 People Responded

Study Name: Eprontia

| Total | 27 | 44 | 30 | 35 | |
|---|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **CPOE** | **VOICE** | **INPATIENT** | **TOTAL** |
| EMPRO | 0 | 1 | 0 | 0 | 1 |
| EPRANTIA | 0 | 0 | 3 | 0 | 3 |
| EPRATIA | 0 | 0 | 2 | 0 | 2 |
| EPRONTIA | 26 | 43 | 21 | 33 | 123 |
| EPRONTIO | 1 | 0 | 0 | 0 | 1 |
| EPRONTYA | 0 | 0 | 1 | 0 | 1 |
| EPROPTIA | 0 | 0 | 0 | 1 | 1 |
| EPRORTIA | 0 | 0 | 0 | 1 | 1 |
| EPROTHIA | 0 | 0 | 1 | 0 | 1 |
| EYPRONTIA | 0 | 0 | 1 | 0 | 1 |
| YPRONTIA | 0 | 0 | 1 | 0 | 1 |

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

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 1. | Eprontia*** | 100 | Subject of this review. |
| 2. | Pronto | 72 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Pr-) and suffixes (-tia vs -to) provide some differentiation. Specifically, the names begin with different first letters, and Eprontia contains the downstroke letter "p" in the second position whereas Pronto does not contain any downstroke letters. Further, Eprontia contains the dotted letter "i" in the suffix, whereas Pronto does not contain any dotted letters. In addition, Eprontia contains 8 letters whereas Pronto only contains 6 letters which gives the names different shapes when written.<br><br>Phonetically, the first syllables (ee vs pron) and second syllables (pron vs toe) sound different. Eprontia also contains two additional syllables.<br><br>Furthermore, none of the following product characteristics directly overlap: strength (25 mg/mL vs 4%/0.33%), dosage form (solution vs shampoo) route of administration (oral vs topical), dose (25 mg to 400 mg or (b) (4) vs apply liberally), and frequency of administration (once or twice daily vs one-time, may repeat in 7-10 days) which may provide additional differentiation if included. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| 3. | Procentra | 70 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Pr-) and suffixes (-tia vs -tra) provide some differentiation. Specifically, the names begin with different first letters, and Eprontia contains the downstroke letter "p" in the second position whereas Procentra does not contain any downstroke letters. Further, Eprontia contains the dotted letter "i" in the suffix, whereas Procentra does not contain any dotted letters.<br><br>Phonetically, the first syllables (ee vs pro), second syllables (pron vs sen), and third syllables (tee vs tra) sound different. Eprontia also contains an extra syllable.<br><br>Furthermore, the product strength does not directly overlap (25 mg/mL vs 5 mg/mL), which may provide additional differentiation if included. |
| 4. | Prometa | 70 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Pr-) and suffixes (-tia vs -ta) provide some differentiation. Specifically, the names begin with different first letters, and Eprontia contains the downstroke letter "p" in the second position whereas Prometa does not contain any downstroke letters. Further, Eprontia contains the dotted letter "i" in the |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Orthographic and/or phonetic differences in the names sufficient to prevent confusion**<br><br>**Other prevention of failure mode expected to minimize the risk of confusion between these two names.** |
|---|---|---|---|
| | | | suffix, whereas Prometa does not contain any dotted letters.<br><br>Phonetically, the first syllables (ee vs pro), second syllables (pron vs meh), and third syllables (tee vs tah) sound different. Eprontia also contains an extra syllable.<br><br>Furthermore, the product strength (25 mg/mL vs 0.4%, 0.6%, 2 mg/mL, 10 mg, and 20 mg) does not directly overlap, which may provide additional differentiation if included. |

**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. | Prempro | 61 |
| 2. | Protopic | 60 |
| 3. | Deponit | 58 |
| 4. | Entresto | 55 |
| 5. | Pine Tar | 54 |
| 6. | Panretin | 53 |
| 7. | Pentolair | 52 |
| 8. | Retin-A | 52 |
| 9. | Perox-A-Mint | 50 |
| 10. | Preparation H | 50 |

**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:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | (b) (4)*** | 68 | This name pair has sufficient orthographic and phonetic differences. |
| 2. | Ceprotin | 68 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Ce-) and infixes (-ron- vs -pro-) provide some differentiation.<br><br>Phonetically, the onset of the first syllables (ee vs see) and offset of the second syllables (pron vs pro) and third syllables (tee vs tin) sound different. Eprontia also contains an extra syllable.<br><br>Furthermore, none of the following product characteristics directly overlap: strength (25 mg/mL vs 500 international units, 1,000 international units), dosage form (solution vs injection), and route of administration (oral vs intravenous) which may provide additional differentiation if included. |
| 3. | Propecia | 68 | This name pair has sufficient orthographic and phonetic differences. |
| 4. | Econtra | 66 | This name pair has sufficient orthographic and phonetic differences. |
| 5. | Cerinta | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 6. | Neurontin | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 7. | Portia-21 | 64 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 8. | Portia-28 | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 9. | Prolensa | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 10. | Promacta | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 11. | Prostin E2 | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 12. | Proventil | 64 | This name pair has sufficient orthographic and phonetic differences. |
| 13. | Intron A | 63 | This name pair has sufficient orthographic and phonetic differences. |
| 14. | Peroxin A | 63 | This name pair has sufficient orthographic and phonetic differences. |
| 15. | Peroxin A 10 | 63 | This name pair has sufficient orthographic and phonetic differences. |
| 16. | Eprosartan | 62 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, the infixes (-ron- vs -rosar-) and suffixes (-tia vs -tan) provide sufficient differentiation. In addition, Eprontia only has 8 letters whereas Eprosartan has 10 letters.<br><br>Phonetically, the offset of the second syllables (pron vs pro), third syllables (tee vs sar), and offset of the fourth syllables (tia vs tan) sound different. |
| 17. | Etrafon-A | 62 | This name pair has sufficient orthographic and phonetic differences. |
| 18. | Yieronia | 62 | This name pair has sufficient orthographic and phonetic differences. |
| 19. | Zarontin | 62 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Za-) provide some differentiation. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| | | | Phonetically, the first syllables (ee vs zah), and onset of the second syllables (pron vs ron) and offset of the third syllables (tia vs tin) sound different. Eprontia also contains an extra syllable.<br><br>Furthermore, none of the following product characteristics directly overlap: strength (25 mg/mL vs 250 mg and 5 mg/mL), and dosage form (solution vs capsule and syrup), which may provide additional differentiation if included. |
| 20. | Strontium | 61 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, the prefixes (Ep- vs St-) and suffixes (-tia vs -tium) provide sufficient differentiation.<br><br>Phonetically, the first syllables (ee vs stron), second syllables (pron vs tee), and third syllables (ah vs um) sound different. Eprontia also contains an extra syllable. |
| 21. | Strontium-89 | 61 | See PFM for Strontium.<br><br>Additionally, the modifier 89 is present in Strontium-89, which provides differentiation, if used. |
| 22. | Aprodine | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 23. | Bronkaid | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 24. | Deproist | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 25. | Mepron | 60 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 26. | Proactiv | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 27. | Proamatine | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 28. | Prohance | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 29. | Protac | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 30. | Protenate | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 31. | Protopam | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 32. | Repronex | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 33. | Sapropterin | 60 | This name pair has sufficient orthographic and phonetic differences. |
| 34. | Brontex | 59 | This name pair has sufficient orthographic and phonetic differences. |
| 35. | Promapar | 59 | This name pair has sufficient orthographic and phonetic differences. |
| 36. | Edurant | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 37. | Esperoct | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 38. | Estro-Span | 58 | This name pair has sufficient orthographic and phonetic differences |
| 39. | Ibrance | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 40. | Procardia | 58 | This name pair has sufficient orthographic, phonetic, and product characteristic differences.<br><br>Orthographically, the prefixes (Ep- vs Pro-) provide some differentiation.<br><br>Phonetically, the first syllables (ee vs pro) and second syllables (pron vs car), and the onset of the third syllables (dee vs tee) sound different. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| | | | Furthermore, none of the following product characteristics directly overlap: strength (25 mg/mL vs 10 mg and 20 mg), and dosage form (solution vs capsule), which may provide additional differentiation if included. |
| 41. | Procto-Pak | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 42. | Profenal | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 43. | Prolia | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 44. | Proventil Hfa | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 45. | Tiopronin | 58 | This name pair has sufficient orthographic and phonetic differences. |
| 46. | Utrona-C | 58 | This name pair has sufficient orthographic and phonetic differences |
| 47. | (b) (4) *** | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 48. | Estropipate | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 49. | Etidronate | 57 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, the prefixes (Ep- vs Etid-) and suffixes (-tia vs -te) provide sufficient differentiation.<br><br>Phonetically, the second syllables (pron vs tid), third syllables (tee vs ron), and fourth syllables (tia vs ate) sound different. |
| 50. | Naproxen | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 51. | Periostat | 57 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 52. | Persantine | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 53. | Prometrium | 57 | This name pair has sufficient orthographic and phonetic differences. |
| 54. | Celontin | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 55. | Egrifta | 56 | This name pair has sufficient orthographic and phonetic differences.<br><br>Orthographically, the infixes (-ron- vs -rif-) and suffixes (-tia vs -ta) provide sufficient differentiation.<br><br>Phonetically, the second syllables (pron vs grif) and offset third syllables (tee vs tah) sound different. Eprontia also contains an extra syllable. |
| 56. | (b) (4)*** | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 57. | Epoetin Beta | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 58. | Estrostep 21 | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 59. | Lupron Depot | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 60. | Peppermint Oil | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 61. | Ponatinib | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 62. | Procto-Kit | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 63. | Prolastin | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 64. | Promacot | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 65. | Promethegan | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 66. | Proprinal | 56 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | **POCA Score (%)** | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 67. | Protostat | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 68. | Reprexain | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 69. | Treprostinil | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 70. | Trientine | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 71. | Vitron-C | 56 | This name pair has sufficient orthographic and phonetic differences. |
| 72. | (b) (4)*** | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 73. | Brontuss | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 74. | Eltroxin | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 75. | Procaine | 55 | This name pair has sufficient orthographic and phonetic differences. |
| 76. | Ferotrin | 54 | This name pair has sufficient orthographic and phonetic differences. |
| 77. | Maprotiline | 54 | This name pair has sufficient orthographic and phonetic differences. |
| 78. | Protonix | 54 | This name pair has sufficient orthographic and phonetic differences. |
| 79. | Pretomanid | 53 | This name pair has sufficient orthographic and phonetic differences. |
| 80. | Parnate | 52 | This name pair has sufficient orthographic and phonetic differences. |
| 81. | Paroxetine | 52 | This name pair has sufficient orthographic and phonetic differences. |
| 82. | Pontocaine | 52 | This name pair has sufficient orthographic and phonetic differences. |
| 83. | Tepotinib | 52 | This name pair has sufficient orthographic and phonetic differences. |
| 84. | (b) (4)*** | 51 | This name pair has sufficient orthographic and phonetic differences. |
| 85. | Interferon-Beta | 51 | This name pair has sufficient orthographic and phonetic differences. |

| No. | **Proposed name:** Eprontia<br>**Established name:** topiramate<br>**Dosage form:** solution<br>**Strength(s):** 25 mg/mL<br>**Usual Dose:** 25 mg to 400 mg (b) (4) | POCA Score (%) | **Prevention of Failure Mode**<br><br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 86. | Interferon Beta-1A | 50 | This name pair has sufficient orthographic and phonetic differences. |
| 87. | Pamidronate | 50 | This name pair has sufficient orthographic and phonetic differences. |
| 88. | Epoetin Alfa | 49 | This name pair has sufficient orthographic and phonetic differences. |
| 89. | Metopirone | 48 | This name pair has sufficient orthographic and phonetic differences. |
| 90. | (b) (4) *** | 47 | This name pair has sufficient orthographic and phonetic differences. |
| 91. | Pentacarinat | 47 | 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 (%) |
|---|---|---|
| | 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. | Prantal | 68 | Brand discontinued with no generic equivalents available. NDA 008114 withdrawn FR effective 11/15/1990. |
| 2. | Eprident | 66 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 3. | Prolintane | 66 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 4. | Aprotinin | 65 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 5. | (b) (4)*** | 64 | Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA ( (b) (4) dated (b) (4)). Subsequently, the proposed proprietary name (b) (4)*** was found conditionally acceptable for NDA (b) (4). |
| 6. | Bronitin | 64 | Brand discontinued with no generic equivalents available. NDA 016126 withdrawn FR effective 06/18/2009. |
| 7. | Drontal | 64 | Veterinary product. |
| 8. | Prop-A-Tane | 64 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 9. | Probeta La | 63 | International product formerly marketed in the United Kingdom |
| 10. | Estrone Aq | 62 | Name identified in RxNorm database. Product is deactivated, and no generic equivalents are available. |
| 11. | Profen Ii | 62 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 12. | Prostap 3 | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 13. | Protease | 62 | Product is not a stand-alone drug name. Protease is an active ingredient in Pancrelipase, a multi-ingredient product containing the enzymes: amylase, lipase, and protease. Thus, "protease" cannot be used alone on a prescription. |
| 14. | Protein C | 62 | Product is not a drug. It is autoprothrombin IIA and blood coagulation factor XIV. |
| 15. | Protein S | 62 | Product is not a drug. It is a vitamin K-dependent plasma glycoprotein synthesized in the liver. In the circulation, Protein S exists in two forms: a free form and a complex form bound to complement protein C4b-binding protein. In humans, protein S is encoded by the PROS1 gene. |
| 16. | Proteins | 62 | Product is not a drug. Chemically, proteins are composed of amino acids, which are organic compounds made of carbon, hydrogen, nitrogen, oxygen or sulfur. Proteins are the building blocks of body tissue and can serve as a fuel source. |
| 17. | Pro-Vent | 62 | International drug product formerly marketed in Ireland and United Kingdom. |
| 18. | Stepronin | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 19. | 82 Strontium | 61 | Product is not a drug. It is a diagnostic radiochemical. |
| 20. | 85 Strontium | 61 | Product is not a drug. It is a diagnostic radiochemical. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 21. | Epanutin | 61 | International product marketed in Austria, Czech Republic, Greece, Hungary, Ireland, Israel, Netherlands, Poland, South Africa, Spain, Sweden, Turkey, and the United Kingdom; and formerly marketed in Germany, Belgium, Spain, and Switzerland. |
| 22. | Metronidale | 61 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 23. | Promectin | 61 | Veterinary product. |
| 24. | Edronax | 60 | International product marketed in Australia, Austria, Belgium, Denmark, Finland, Hungary, Ireland, Israel, Italy, Mexico, Norway, New Zealand, Poland, Portugal, South Africa, Sweden, Switzerland, Thailand, Turkey, and the United Kingdom, and formerly marketed in Germany, Russia, and the Czech Republic. |
| 25. | Eprinex | 60 | Veterinary product. |
| 26. | Fepron | 60 | International product formally marketed in Italy, Netherlands and Belgium |
| 27. | Fipronil | 60 | Veterinary product. |
| 28. | Iproniazid | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 29. | Meprospan | 60 | Brand discontinued with no generic equivalents available. NDA 011284 withdrawn FR effective 10/2/1996. |
| 30. | Nupro Neutral | 60 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available |
| 31. | Propane | 60 | Product is not a drug. It is a by-product of natural gas processing and petroleum refining, commonly used as a fuel. |
| 32. | Promacet | 59 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 33. | Promit | 59 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 34. | Protilase | 59 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 35. | Serentil | 59 | Brand discontinued with no generic equivalents. NDA 016774, NDA 016775, and NDA 016997 withdrawn FR effective 03/26/2018. |
| 36. | Tronothane | 59 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 37. | (b) (4)*** | 59 | Proposed proprietary name for IND 073916 found unacceptable by DMEPA (OSE# 2018-21548167-1 dated 04/22/2019). Subsequently, the proposed proprietary name, Rukobia*** was found conditionally acceptable for IND 073916 and NDA 212950. |
| 38. | Cerenia | 58 | Veterinary product. |
| 39. | Cyprostat | 58 | International drug product marketed in Australia and United Kingdom. |
| 40. | Droncit | 58 | Veterinary product. |
| 41. | Enterocina | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 42. | Eprazinone | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 43. | Eprozinol | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 44. | Estro-Span 40 | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 45. | Etretinate | 58 | Brand discontinued with no generic equivalents available. NDA 019369 withdrawn FR effective 09/10/2003. |
| 46. | Mepranix | 58 | International product formerly marketed in the United Kingdom. |
| 47. | Nitronal | 58 | Brand discontinued with no generic equivalents available. NDA 018672 withdrawn FR effective 9/13/2000. |
| 48. | Pentran | 58 | International product formerly marketed in the UK. |
| 49. | Piperonal | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 50. | Pro Otic | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 51. | Profen La | 58 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 52. | Prompt | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 53. | Prondol | 58 | International product formerly marketed in the United Kingdom and Ireland. |
| 54. | Pronestyl | 58 | Brand discontinued with no generic equivalents available. NDA 007335 and NDA 017371 withdrawn FR effective 03/13/2009. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 55. | Pronto Spray | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 56. | Prostep | 58 | Brand discontinued with no generic equivalents available. NDA 019983 was withdrawn FR effective 06/18/2009. |
| 57. | Protamone | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 58. | Protropin | 58 | Brand discontinued with no generic equivalents available. NDA 019107 withdrawn FR effective 06/16/2006. |
| 59. | Teronac | 58 | International product marketed in Indonesia, and formerly marketed in Hungary, Ireland, Israel, Netherlands, Singapore, Switzerland, Greece, the United Kingdom, Germany, and South Africa. |
| 60. | Trionate | 58 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 61. | Emepronium | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 62. | Medronate | 57 | International product formerly marketed in Brazil. |
| 63. | Propothesia | 57 | Veterinary product. |
| 64. | Quibron-T | 57 | Brand discontinued with no generic equivalents available. ANDA 088656 withdrawn FR effective 06/18/2009. |
| 65. | Brondil | 56 | International product marketed in the Philippines and formerly marketed in Thailand. |
| 66. | Eprex | 56 | International product marketed in Canada, Hong Kong, Turkey, Australia, Belgium, Brazil, Czech Republic, Denmark, Finland, France, Greece, Ireland, Israel, Italy, Mexico, Netherlands, Norway, New Zealand, Poland, Portugal, Spain, Sweden, Switzerland, Thailand, United Kingdom, Venezuela, Malaysia, South Africa, Singapore, Indonesia, Philippines, France, India, and Russia; and formerly marketed in Argentina, Germany, Hungary, and Chile. |
| 67. | Eprinomectin | 56 | Veterinary product. |
| 68. | Eprizero | 56 | Veterinary product. |
| 69. | Epsiprantel | 56 | Veterinary product. |
| 70. | Ferronate | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 71. | Ponstan | 56 | International product marketed in Australia, India, United Kingdom, Canada, Ireland, Brazil, Finland, Greece, Hong Kong, Indonesia, Malaysia, Mexico, New Zealand, Philippines, Portugal, South Africa, Switzerland, Thailand, Turkey, Venezuela, and formerly marketed in Singapore. |
| 72. | Probanthine | 56 | Brand discontinued with no generic equivalents available. NDA 008732 was withdrawn FR effective 07/21/2017 and NDA 008843 was withdrawn FR effective 06/10/1999. |
| 73. | Procanbid | 56 | Brand discontinued with no generic equivalents available. NDA 020545 withdrawn FR effective 06/18/2009. |
| 74. | Prodip | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 75. | Prolactin | 56 | Product is not a drug. It is a hormone released from the anterior pituitary gland that stimulates milk production after childbirth. |
| 76. | Propacet | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 77. | Propacet 100 | 56 | Brand discontinued with no generic equivalents available. ANDA 070107 withdrawn FR effective 01/22/1999. |
| 78. | Propade | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 79. | Propan | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 80. | Propet | 56 | Veterinary product. |
| 81. | Propine | 56 | Brand discontinued with no generic equivalents available. NDA 018239 withdrawn FR effective 07/21/2017. |
| 82. | Propionate | 56 | Product is not a drug. It is a salt or ester of propionic acid. |
| 83. | Prothiaden | 56 | International drug product marketed in Australia, India, Malaysia, South Africa, Japan, United Kingdom, Belgium, Denmark, Ireland, France, Netherlands, and Czech Republic; and formerly marketed in several countries including Hong Kong, New Zealand, Philippines, Singapore, Thailand, and Spain. |
| 84. | Reproterol | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 85. | Roferon-A | 56 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 86. | Spiroctan | 56 | International drug product marketed in Brazil, and formerly marketed in Venezuela, Switzerland, Netherlands, France, and United Kingdom. |
| 87. | Timpron 250 Ec | 56 | International product formerly marketed in the United Kingdom. |
| 88. | Timpron 500 Ec | 56 | International product formerly marketed in the United Kingdom. |
| 89. | 1,3-propanediol | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 90. | Cyprodenate | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 91. | (b) (4)*** | 55 | Proposed proprietary name found conditionally acceptable under IND (b) (4) on (b) (4) ((b) (4)). IND (b) (4) was withdrawn effective (b) (4). |
| 92. | Estroplan | 55 | Veterinary product. |
| 93. | Kronofed-A | 55 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 94. | Naprofen | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 95. | Ospa Protein | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 96. | Pro Dine 5000C | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 97. | Pro1tek | 55 | Not a drug product. It is a hand sanitizer. |
| 98. | Promace | 55 | Veterinary product. |
| 99. | Propanix La | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 100. | Protamines | 55 | Product is not a drug. Protamines are small basic proteins that replace histones in the nucleus of the spermatozoa causing an increase in the folding of the DNA and thus leaving it more protected. |
| 101. | Saffron Stain | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 102. | Potiga | 54 | Brand discontinued with no generic equivalents available. NDA 022345 withdrawn FR effective 11/02/2017. |
| 103. | Propanix | 54 | International drug product formerly marketed in United Kingdom. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 104. | Pricortin | 53 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 105. | Pri-Cortin 50 | 53 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 106. | 2-Nitropropane | 52 | Product is not a drug. It is a hydrocarbon used as a solvent. |
| 107. | Aceprometazine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 108. | Enaprilat | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 109. | Entaprin | 52 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 110. | Proketazine | 52 | Brand discontinued with no generic equivalents available. NDA 012768 was withdrawn FR effective 11/05/1992. NDA 014173 was withdrawn FR effective 09/04/1996. |
| 111. | Propantheline | 52 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available |
| 112. | Tropatepine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 113. | Epoetin delta | 52 | Active ingredient of a withdrawn international investigational product. |
| 114. | Therapentin-90 | 51 | Name identified in RxNorm database. Product is deactivated and no generic equivalents are available. |
| 115. | Piriton | 50 | International drug product marketed in Ireland, United Kingdom, Hong Kong, and Singapore, and formerly marketed in Australia and Thailand. |
| 116. | Serotonin | 50 | Product is not a drug. It is a neurotransmitter. |
| 117. | Tiaprofenate | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 118. | 1,2-Propanedithiol | 49 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 119. | Betaprone | 49 | Brand discontinued with no generic equivalents available. NDA 011657 withdrawn FR effective 04/26/1996. |
| 120. | 1,2-Propanediamine | 48 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 121. | Pear Preparation | 47 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 122. | Diptheria Protein | 46 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 123. | Oats Preparation | 46 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 124. | Persantin Retard | 46 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 125. | Pro Pet Antiseptic | 46 | Veterinary product. |
| 126. | Prothionamide | 46 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 127. | Tuna Preparation | 46 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 128. | Tripe Preparation | 44 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 129. | Valepotriate | 44 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 130. | Empro | 44 | Name identified in FDA Prescription Simulation Study. Product is deactivated and no generic equivalents are available. |
| 131. | Retinyl Propionate | 41 | 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 (%) |
|---|---|---|
| 1. | Kerendia*** | 65 |
| 2. | (b) (4)*** | 64 |
| 3. | Orencia | 64 |
| 4. | Atrovent | 63 |
| 5. | Pramotic | 63 |

[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 (%) |
|---|---|---|
| 6. | (b) (4)*** | 62 |
| 7. | Aprindine | 62 |
| 8. | Aptensio | 62 |
| 9. | (b) (4)*** | 62 |
| 10. | Prandimet | 62 |
| 11. | Prandin | 62 |
| 12. | Primatene | 62 |
| 13. | Trental | 62 |
| 14. | Primperan | 61 |
| 15. | Brom Tann Pe | 60 |
| 16. | Bromtapp | 60 |
| 17. | Fybranta | 60 |
| 18. | (b) (4)*** | 60 |
| 19. | Iprindole | 60 |
| 20. | Nitrotan | 60 |
| 21. | Prenexa | 60 |
| 22. | Pre-Op Ii | 60 |
| 23. | Prestalia | 60 |
| 24. | Preventeza | 60 |
| 25. | Pyrantel | 60 |
| 26. | Sprintec | 60 |
| 27. | (b) (4)*** | 60 |
| 28. | Trokendi | 60 |
| 29. | Yutrepia*** | 60 |
| 30. | Atropine | 59 |
| 31. | Atropine-1 | 59 |
| 32. | Principen | 59 |
| 33. | Principen '125' | 59 |
| 34. | Principen '250' | 59 |
| 35. | Principen '500' | 59 |
| 36. | Trandate | 59 |
| 37. | Aphrodyne | 58 |
| 38. | Atropen | 58 |
| 39. | Bromatan | 58 |
| 40. | Bromatapp | 58 |
| 41. | Copper Edta | 58 |
| 42. | Droxia | 58 |
| 43. | (b) (4)*** | 58 |
| 44. | Nitrostat | 58 |
| 45. | Nitrotab | 58 |
| 46. | (b) (4)*** | 58 |
| 47. | Orlenta | 58 |
| 48. | (b) (4)*** | 58 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 49. | Pentane | 58 |
| 50. | Piroctone | 58 |
| 51. | Predfoam | 58 |
| 52. | Psorent | 58 |
| 53. | Suprenza | 58 |
| 54. | Triptone | 58 |
| 55. | Ixempra | 57 |
| 56. | Nitro-Par | 57 |
| 57. | Pentasa | 57 |
| 58. | Treanda | 57 |
| 59. | Tripedia | 57 |
| 60. | (b) (4)*** | 56 |
| 61. | Aprepitant | 56 |
| 62. | Aprinox | 56 |
| 63. | Atrac-Tain | 56 |
| 64. | Besponsa | 56 |
| 65. | Bion Tears | 56 |
| 66. | Brilinta | 56 |
| 67. | Coro-Nitro | 56 |
| 68. | Ircon-Fa | 56 |
| 69. | Irenka | 56 |
| 70. | Metrotop | 56 |
| 71. | Orenitram | 56 |
| 72. | Perestan | 56 |
| 73. | Photrexa | 56 |
| 74. | Prednicot | 56 |
| 75. | Prezista | 56 |
| 76. | Replesta | 56 |
| 77. | Trinessa | 56 |
| 78. | Trintex | 56 |
| 79. | Votrient | 56 |
| 80. | (b) (4)*** | 56 |
| 81. | Zeposia | 56 |
| 82. | Altorant | 55 |
| 83. | Depandro 100 | 55 |
| 84. | Ditropan | 55 |
| 85. | (b) (4)*** | 55 |
| 86. | (b) (4)*** | 55 |
| 87. | Intropin | 55 |
| 88. | Irinotecan | 55 |
| 89. | Krintafel | 55 |
| 90. | Nephroscan*** | 55 |
| 91. | Pentopak | 55 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 92. | Pimtrea | 55 |
| 93. | Pramosone | 55 |
| 94. | Prinzide | 55 |
| 95. | Pur-In Neutral | 55 |
| 96. | Trandide | 55 |

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