CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216513Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	December 21, 2021
Application Type and Number:	NDA 216513
Product Name and Strength:	Pheburane (sodium phenylbutyrate) oral pellets, 483 mg/g
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Medunik Canada Inc (Medunik)
PNR ID #:	2021-1044724200
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Pheburane, 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. Medunik submitted an external name study, conducted by [redacted] (b) (4), for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 22, 2021.

- Intended Pronunciation: fe' bue rayne
- Active Ingredient: sodium phenylbutyrate
- Indication of Use: An adjunctive therapy in the chronic management of urea cycle disorders, involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase [redacted] (b) (4)
- Route of Administration: Oral
- Dosage Form: oral pellets
- Strength: 483 mg/g [a]
- Dose and Frequency:
  - 450–600 mg/kg/day [redacted] (b) (4) weighing less than 20 kg
  - 9.9–13 g/m^2/day [redacted] (b) (4) weighing more than 20 kg, [redacted] (b) (4)
  - The total daily dose should be divided [redacted] (b) (4) and given with [redacted] (b) (4) meal [redacted] (b) (4).
- How Supplied:
  - [redacted] (b) (4) 84 g of sodium phenylbutyrate per bottle. A calibrated dosing spoon which dispenses up to 3 g of sodium phenylbutyrate [redacted] (b) (4), is provided in the packaging.
- Storage: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F)

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[a] Request for Proprietary Name Review [redacted] (b) (4) From internal discussion with OPQ, we understand the strength statement [redacted] (b) (4) is currently under review. [redacted] (b) (4)

- Reference Listed Drug/Reference Product: Buphenyl

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Pheburane would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Rare Diseases and Medical Genetics (DRDMG) concurred with the findings of OPDP's assessment for Pheburane.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 Comments from Other Review Disciplines at Initial Review

On September 13, 2021, the Division of Rare Diseases and Medical Genetics (DRDMG) did not forward any comments or concerns relating to Pheburane at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

One hundred and eight (n=108) practitioners participated in DMEPA's prescription studies for Pheburane. We note 3 study participants in the inpatient study responded with (b) (4) *** (n=1) or (b) (4) *** (n=2). However, it appears that these responses were placed in the wrong entry field and were actually responses to other study names in the prescription simulation study. Thus, we determined these responses to be invalid. The remaining responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies.

[b] USAN stem search conducted on October 8, 2021.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 265 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search, and (b) (4) external 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: combined match percentage score ≥70%	5
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	243
Low similarity name pair: combined match percentage score ≤54%	20

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

Our analysis of the 268 names contained in Table 1 determined none of the names will pose a risk for confusion with Pheburane as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

On December 21, 2021, DMEPA 2 communicated our findings to the Division of Rare Diseases and Medical Genetics (DRDMG).

3 CONCLUSION

The proposed proprietary name, Pheburane, is acceptable.

If you have any questions or need clarifications, please contact Su-Lin Sun, OSE project manager, at 301-796-0036.

3.1 COMMENTS TO MEDUNIK CANADA INC

[c] POCA search conducted on October 8, 2021 in version 4.4.

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

If any of the proposed product characteristics as stated in your submission, received on September 22, 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. [d]

[d] 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[e]. 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

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

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

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

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

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

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

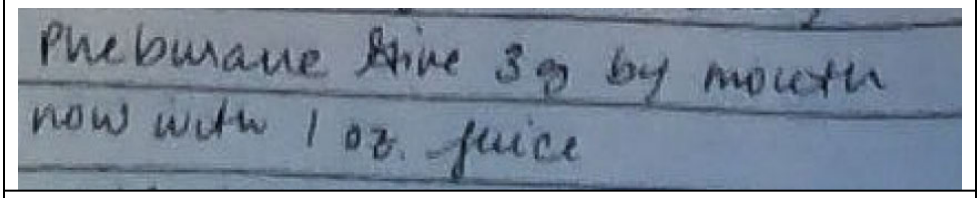
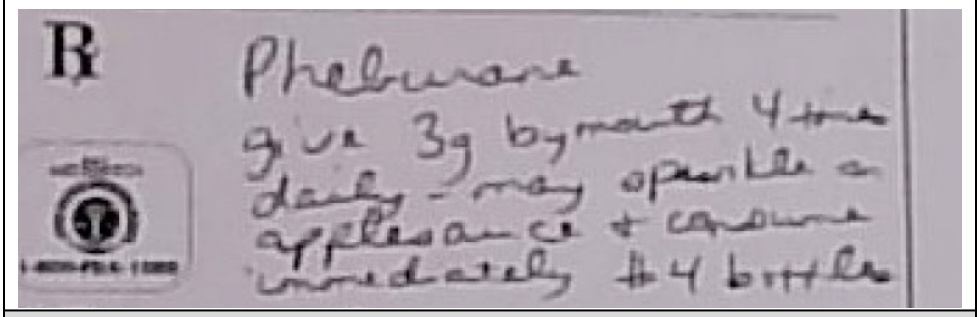
Appendix A1: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

Appendix B: Prescription Simulation Samples and Results

Figure 1. Pheburane Study (Conducted on October 8, 2021)

Handwritten Medication Order/Prescription	**Verbal Prescription**
Medication Order:  Outpatient Prescription:  **CPOE Study Sample (displayed as sans-serif, 12-point, bold font)** Pheburane	Pheburane Give 3 grams by mouth 4 times daily. May sprinkle on applesauce and consume immediately.

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Pheburane

263 People Received Study

108 People Responded

Total	27	26	29	26	
INTERPRETATION	OUTPATIENT	CPOE	VOICE	INPATIENT	TOTAL
(b) (4)	0	0	0	1	1
FEBRUAIN	0	0	1	0	1
FEBRUANE	0	0	1	0	1
FEBRUAYN	0	0	1	0	1
FEBRURAIN	0	0	2	0	2
FEBRUREIN	0	0	1	0	1
FEBRURING	0	0	1	0	1
FEBURAIN	0	0	9	0	9
FEBURAIND	0	0	1	0	1
FEBURAINE	0	0	1	0	1
FEBURANE	0	0	6	0	6
FEBURAYNE	0	0	1	0	1
FEBURIN	0	0	1	0	1
PHEBRIANE	1	0	0	0	1
PHEBRUANE	0	0	0	1	1
PHEBUANE	1	0	0	0	1
PHEBUIANE	1	0	0	0	1
PHEBURANE	15	26	0	22	63
PHEBURONE	1	0	0	0	1
PHEBUSANE	1	0	0	0	1
PHELRUANE	1	0	0	0	1
PHELURANE	5	0	0	0	5
PHLEBURANA	1	0	0	0	1
(b) (4)	0	0	0	2	2
VEBURAIN	0	0	1	0	1
VEBURANE	0	0	2	0	2

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

No.	**Proposed name:** Pheburane **Established name:** sodium phenylbutyrate **Dosage form:** oral pellets **Strength(s):** 483 mg/g **Usual Dose:** 450–600 mg/kg/da (b) (4) eighing less than 20 kg; or 9.9–13 g/m2 /day (b) (4) weighing more than 20 kg, (b) (4).	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Pheburane	100	Proposed proprietary name subject of this review.
2.	Phenurone	86	Brand discontinued with no generic equivalents available. NDA 007707 withdrawn FR effective 6/4/2004.
3.	Suprane	73	Orthographically, this name pair starts with different letters 'P' vs 'S' and Pheburane has an upstroke at infix 4th position 'b' while Suprane has a downstroke at 3rd position 'p.' Phonetically, the first (fe' vs soo) and second (bue vs. prane) syllables sound different and Pheburane contains an additional syllable.
4.	Ephedrine	70	Orthographically, the name pair starts with different letters (P vs. E), and Ephedrine has a downstroke at 2nd position 'p.'. Phonetically, the first (fe' vs. ee), second (bu vs. fed), and third (rayne vs. rin) syllables sound different.
5.	Phenergan	70	Orthographically, the infixes and suffixes of this name pair appear different when scripted with Pheburane containing upstroke at 4th position 'b' and Phenergan containing downstroke in 7th position 'g'. Phonetically, the second (bue vs. er) and third (rayne vs. gan) syllables sound different.

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.	Pacerone	68
2.	Bydureon	65
3.	Zephiran	65
4.	Panretin	62
5.	Pentran	62
6.	Premarin	62
7.	Rice Bran	62
8.	Sebulon	62
9.	Suphedrin	62
10.	Suphedrine	62
11.	Serophene	61
12.	Phentride	60
13.	Pharmadine	58
14.	Zetran	58
15.	Phentermine	58
16.	Femadrine	58
17.	Durolane	57
18.	Glyburide	57
19.	Banophen	56
20.	Duralone	56
21.	Orphenadrine	56
22.	Fabrazyme	56
23.	Fiber Tab	56
24.	Fibryna***	56
25.	Hydropane	56
26.	Senormin	56
27.	Phrenilin	56
28.	Pramosone	56
29.	Prasterone	56
30.	Zenatane	56
31.	Glyburase	55
32.	Finerenone	55
33.	Penederm	55
34.	Percolone	55
35.	Phenabid	55

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:** Pheburane **Established name:** sodium phenylbutyrate **Dosage form:** oral pellets **Strength(s):** 483 mg/g **Usual Dose:** 450–600 mg/kg/da (b) (4) weighing less than 20 kg; or 9.9–13 g/m2 /day (b) (4) weighing more than 20 kg. (b) (4)	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Phenazine 50	68	This name pair has sufficient orthographic and phonetic differences. This is a deactivated proprietary name for promethazine injection. Pheburane and promethazine injection differ in strength (483 mg/g vs. 25 mg/mL or 50 mg/mL), dose (450-600 mg/kg/day or 9.9-13 g/m^2/day vs. 12.5 to 25 mg), dosage form (oral pellets vs. injection), and route of administration (oral vs. intravenous or intramuscular).
2.	Phenerzine	66	This name pair has sufficient orthographic and phonetic differences. This is a deactivated proprietary name for promethazine injection. Pheburane and promethazine injection differ in strength (483 mg/g vs. 25 mg/mL or 50 mg/mL), dose (450-600 mg/kg/day or 9.9-13 g/m^2/day vs. 12.5 to 25 mg), dosage form (oral pellets vs. injection), and route of administration (oral vs. intravenous or intramuscular).
3.	Fiber Eze	62	This name pair has sufficient orthographic and phonetic differences.
4.	Pap-Urea	62	This name pair has sufficient orthographic and phonetic differences.
5.	Pedural	62	This name pair has sufficient orthographic and phonetic differences.
6.	Zemuron	62	This name pair has sufficient orthographic and phonetic differences.
7.	Ethrane	61	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Pheburane **Established name:** sodium phenylbutyrate **Dosage form:** oral pellets **Strength(s):** 483 mg/g **Usual Dose:** 450–600 mg/kg/day (b) (4) weighing less than 20 kg; or 9.9–13 g/m2 /day (b) (4) weighing more than 20 kg, (b) (4) .	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
8.	Bebulin	60	This name pair has sufficient orthographic and phonetic differences.
9.	Edurant	60	This name pair has sufficient orthographic and phonetic differences.
10.	Forane	60	This name pair has sufficient orthographic and phonetic differences.
11.	Phenelzine	60	This name pair has sufficient orthographic and phonetic differences. Additionally, the drugs differ in strength (483 mg/g vs. 15 mg), dose (450-600 mg/kg/day or 9.9-13 g/m^2/day vs. 15 mg or 1 tablet), and dosage form (oral pellets vs. tablet).
12.	Probuphine	59	This name pair has sufficient orthographic and phonetic differences.
13.	Desflurane	58	This name pair has sufficient orthographic and phonetic differences.
14.	Matulane	58	This name pair has sufficient orthographic and phonetic differences.
15.	Panheprin	58	This name pair has sufficient orthographic and phonetic differences.
16.	Paredrine	58	This name pair has sufficient orthographic and phonetic differences.
17.	Sevoflurane	58	This name pair has sufficient orthographic and phonetic differences.
18.	Phenol Ez	58	This name pair has sufficient orthographic and phonetic differences.
19.	Fibercon	57	This name pair has sufficient orthographic and phonetic differences.
20.	Phenylbutyrate	57	This name pair has sufficient orthographic and phonetic differences.
21.	Phenyl Butyrate	57	This name pair has sufficient orthographic and phonetic differences.
22.	Femiron	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name:** Pheburane **Established name:** sodium phenylbutyrate **Dosage form:** oral pellets **Strength(s):** 483 mg/g **Usual Dose:** 450–600 mg/kg/da (b) (4) weighing less than 20 kg; or 9.9–13 g/m2 /day (b) (4) weighing more than 20 kg,	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
23.	Papaverine	56	This name pair has sufficient orthographic and phonetic differences.
24.	Isoflurane	56	This name pair has sufficient orthographic and phonetic differences.
25.	Photofrin	56	This name pair has sufficient orthographic and phonetic differences.
26.	Phen-Tuss Ad	56	This name pair has sufficient orthographic and phonetic differences.
27.	Fibro-Vein	55	This name pair has sufficient orthographic and phonetic differences.
28.	Pediaphen	55	This name pair has sufficient orthographic and phonetic differences.
29.	Abraxane	55	This name pair has sufficient orthographic and phonetic differences.
30.	Permapen	55	This name pair has sufficient orthographic and phonetic differences.
31.	Phenytoin	55	This name pair has sufficient orthographic and phonetic differences.
32.	Psorcon E	55	This name pair has sufficient orthographic and phonetic differences.
33.	Vemurafenib	55	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
1.	Cytovene	54
2.	Nephramine	54
3.	Nephramine 5.4%	54
4.	Puralube	54
5.	Vibisone	54
6.	Cymevene	54
7.	Suphera	54

No.	Name	POCA Score (%)
8.	Phenylephrine	53
9.	Pherazine Dm	53
10.	Alpha.-Cubebene	52
11.	Auraphene-B	52
12.	Peranex	52
13.	Urethane	52
14.	Buprenex	52
15.	Pherazine Vc	51
16.	Urapine	50
17.	Samarium	49
18.	Cybolin-12	48
19.	Phenobarbital	48
20.	Fentora	46

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.	Penthrane	68	Brand discontinued with no generic equivalents available. NDA 013056 withdrawn FR effective 09/17/2001.
2.	Phenazine	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Phenazine-35	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
4.	A-phedrin	67	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Phenzene	67	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
6.	Piperine	67	This is not a drug. It is a compound found in black pepper.
7.	Gabarone	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Hippurate	66	This is not a drug. It is the glycine conjugate of benzoic acid.
9.	Kebuzone	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
10.	Phenolate	66	Product is not drug. Phenolates are anions, salts, and esters of phenols

No.	Name	POCA Score (%)	Failure preventions
11.	Sebutone	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
12.	Sterane	66	Product is not drug. Sterane compounds are a class of 4-cyclic compounds derived from steroids or sterols
13.	Anturane	65	Brand discontinued with no generic equivalents available. NDA 011556 withdrawn FR effective 06/18/2009.
14.	Apaflurane	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Mudrane	64	Name identified in RxNorm database. Brand discontinued with no generic equivalents.
16.	Phenetron	64	Product discontinued with no generic equivalents available. ANDA 080846 withdrawn FR effective 04/10/1991.
17.	Pheniramine	64	International product marketed in India.
18.	Pertofrane	63	Brand discontinued with no generic equivalents available. NDA 013621 withdrawn FR effective 09/04/1996
19.	B-Fedrine	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available
20.	Fumarate	62	Product is not a drug. It is a salt or ester of fumaric acid.
21.	Feprazone	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
22.	Phenothrin	62	Product is not a drug. It is an insecticide.
23.	Tridrane	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	Dipyrone	61	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
25.	Enflurane	61	Product discontinued with no generic equivalents available. ANDA 070803 and ANDA 074396 withdrawn FR effective 11/02/2017 and 07/21/2017, respectively. This is the active ingredient for Ethrane (NDA 017087), which was withdrawn FR effective 11/03/2016.
26.	Fenbufen	60	International drug product marketed in United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
27.	Hippuran I 131	60	Brand discontinued with no generic equivalents available. NDA 016666 withdrawn FR effective 07/08/2011.
28.	Nydrane	60	International product formerly marketed in the United Kingdom.
29.	Peg-12 Laurate	60	Product is not a drug. It is a liquid emulsifier for cosmetic formulations.
30.	Peg-4 Laurate	60	Product is not a drug. It is a liquid emulsifier for cosmetic formulations.
31.	Peg-8 Laurate	60	Product is not a drug. It is the polyethylene glycol ester of Lauric Acid and is used in cosmetics and beauty products as a surfactant and emulsifying agent.
32.	Penbritin	60	International product marketed in United Kingdom
33.	Perazine	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Pharmadrine	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
35.	Phenavent	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
36.	Pholedrine	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Pileran	60	Veterinary product.
38.	Predalone 50	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Supreme	60	Product is not a drug. It is a homeopathic product.
40.	Vinburnine	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Cloburate	59	International product marketed in the United Kingdom.
42.	Duraphen	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
43.	Duraphen 1000	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
44.	Hibitane	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Isobutane	59	Product is not a drug. It is a chemical isomer of butane.

No.	Name	POCA Score (%)	Failure preventions
46.	Peganone	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
47.	Pentane	59	Product is not a drug. It is an organic compound.
48.	Phenesin	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Phenformin	59	International product marketed in Europe, Mexico, and India.
50.	Sebucare	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
51.	Spherulin	59	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
52.	Aphedrid	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
53.	Cetazone	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
54.	Febuprol	58	International product formerly marketed in Germany, Portugal, and Austria.
55.	Fenopron	58	International product formerly marketed in the United Kingdom.
56.	Fepron	58	International product formerly marketed in Belgium, Italy, and Netherland.
57.	Lodrane	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
58.	Lodrane 24	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
59.	Paludrine	58	International product marketed in Singapore, France, Greece, and other foreign countries.
60.	Pedtrace-4	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
61.	Phenacetin	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents.
62.	Phenerbel-S	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
63.	(b) (4) ***	58	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA (OSE# (b) (4) Name or entire application withdrawn by the Applicant.
64.	(b) (4) ***	58	Proposed proprietary name for NDA 208612 found unacceptable by DMEPA (OSE# 2017-19116657 dated 08/11/2020). NDA 208612 approved under the proprietary name Balcoltra.

No.	Name	POCA Score (%)	Failure preventions
65.	Tibolone	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
66.	Pributazone	58	Veterinary product.
67.	Piperazine	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
68.	Phor Pain	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
69.	Phenyldrine	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
70.	Butane	57	Product is not a drug. It is a highly flammable colorless gas.
71.	Taurate	57	Product is not a drug. It is the salt form of the amino acid, taurine
72.	Sakuranin	57	Product is not a drug. It is a type of flavanoid.
73.	Primperan	57	International product marketed and formerly marketed in multiple countries outside of the US.
74.	Barophen	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
75.	Camphene	56	Product is not a drug. It is a compound used in the preparation of fragrances and as a food additive for flavoring.
76.	Cinolone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
77.	Farnesane	56	International product formerly marketed in Japan.
78.	Ferulate	56	Product is not a drug. It is a salt of ferulic acid.
79.	Flurate	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
80.	Fenbutrazate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
81.	Heptane	56	Product is not a drug. Heptane is a straight-chain alkane component of gasoline.
82.	Petrem	56	Veterinary product.
83.	Pharmaseb	56	Veterinary product.
84.	Vetripen	56	Veterinary product.
85.	Zimovane	56	International product marketed in Ireland and the United Kingdom.
86.	Thiophene	56	International product formerly marketed in France.

No.	Name	POCA Score (%)	Failure preventions
87.	Theracran	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
88.	Pemoline	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
89.	Psoralen	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
90.	Phenergan Vc	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
91.	Propane	56	Product is not a drug. It is a by-product of natural gas processing and petroleum refining.
92.	Phloretin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
93.	Phenindione	56	Product is not a drug. It is a powder for compounding not recommended for clinical use.
94.	Pheneen	56	Product is not a drug. It is a disinfectant.
95.	Phenasep	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
96.	Naphtho(2,1-B)Furan	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
97.	Prop-A-Tane	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
98.	Prepadine	55	International product marketed in the United Kingdom.
99.	Picrate	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
100.	Phenylbutazone	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
101.	Prophene 65	55	Product discontinued with no generic equivalents available. ANDA 083538 withdrawn FR effective September 6, 1995.
102.	Pseubrom	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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

No.	Name	POCA Score (%)
1.	Berberine	62
2.	Diaperene	62
3.	Feprazone	62
4.	Heparin	62
5.	Sparine	62
6.	Buspirone	61
7.	Isoprene	61
8.	Thermazene	61
9.	Betaprone	60
10.	Butyrate	60
11.	Cem-Urea	60
12.	Cephradine	60
13.	Fenbufen	60
14.	Securon	60
15.	Securopen	60
16.	Sudrine	60
17.	Synephrine	60
18.	Syprine	60
19.	Zembrace	60
20.	Benzarone	59
21.	Sabinene	59
22.	Spermine	59
23.	Biperiden	58
24.	Buproban	58
25.	Butazone	58
26.	Cephapirin	58
27.	Ethaverine	58
28.	Everone	58
29.	(b) (4) ***	58
30.	Humulene	58
31.	Lamprene	58
32.	Mepergan	58
33.	Serpalan	58
34.	Sibutramine	58
35.	Sudan Red	58

[f] 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 (%)
36.	Supprelin	58
37.	Taurine	58
38.	Tetterine	58
39.	Theodrine	58
40.	Dandrene	57
41.	Endur-Acin	57
42.	Haldrone	57
43.	Ibuprin	57
44.	Naprelan	57
45.	Supramine	57
46.	Tobrasone	57
47.	Alphaparin	56
48.	Bepreve	56
49.	Busprirone	56
50.	Butasone	56
51.	Centrine	56
52.	Ceprotin	56
53.	Cholebrine	56
54.	Dermazene	56
55.	Dibunate	56
56.	Hetrazan	56
57.	Homarine	56
58.	Hyperab	56
59.	Ibudone	56
60.	Kinerase	56
61.	Never Pain	56
62.	Neverpain	56
63.	Riboprine	56
64.	Sarene	56
65.	Seb-Prev	56
66.	Styrene	56
67.	Superfed	56
68.	Syncurine	56
69.	Tetracyn	56
70.	Vetripen	56
71.	Betadren	55
72.	Budeprion	55
73.	Hyperrab	55
74.	Lufenuron	55
75.	Sudatrate	55
76.	Suprofen	55

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