# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 204442Orig1s000

# PROPRIETARY NAME REVIEW(S)

# MEMORANDUM

**REVIEW OF PROPRIETARY NAME**

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)

| | |
|---|---|
| **Date of This Memorandum:** | February 18, 2016 |
| **Requesting Office or Division:** | Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) |
| **Application Type and Number:** | NDA 204442 |
| **Product Name and Strength:** | Probuphine (buprenorphine) implant, 74.2 mg |
| **Submission Date:** | February 16, 2016 |
| **Applicant/Sponsor Name:** | Titan Pharmaceuticals, Inc. |
| **OSE RCM #:** | 2016-2818361 |
| **DMEPA Primary Reviewer:** | Millie Shah, PharmD, BCPS |
| **DMEPA Team Leader:** | Vicky Borders-Hemphill, PharmD |

## 1 PURPOSE OF MEMO

This memorandum is to re-assess the proposed proprietary name, Probuphine, based on the revised strength. The proposed name, Probuphine, was found acceptable in OSE review # 2015-1601445 dated December 8, 2015[1] and OSE review #2012-2724 dated February 11, 2013.[2] The established name of the product was originally presented as the salt, buprenorphine hydrochloride, with the strength of 80 mg per implant. Based on the recommendation by the Office of Product Quality, Titan Pharmaceuticals revised the

[1] Shah M. Proprietary Name Review for Probuphine (NDA 204442). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Dec 08. 68 p. OSE RCM No.: 2015-1601445.

[2] Borders-Hemphill V. Proprietary Name Review for Probuphine (NDA 204442). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 FEB 11. 32 p. OSE RCM No.: 2012-2724.

strength of the product to reflect the active moiety, buprenorphine, as the established name with the revised implant strength of 74.2 mg.

## 2 METHODS AND MATERIALS REVIEWED

For reassessment of the proposed proprietary name, we evaluated previous proprietary name reviews dated December 8, 2015 and February 11, 2013 to assess whether the change in strength would alter our previous conclusion regarding the acceptability of the proposed proprietary name. We searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates.[3] Our search did not identify any USAN stems present in the proprietary name.

We evaluated the results of our previous POCA search in OSE review #2015-1601445[4] to identify names with overlapping strength and/or dose with the new 74.2 mg strength. Our search did not identify any names with an overlap in strength and/or dose with the 74.2 mg strength.

Additionally, since Probuphine is being proposed in a strength that is not commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Probuphine that were not identified in POCA, and found to have an overlap in strength with Probuphine.[5] Our search did not result in any names.

Our USAN stem search, evaluation of previous POCA search results, and eDRLS search did not identify any new names that represent a potential source of drug name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Davis Mathew, OSE Project Manager, at 240-402-4559.

## 4 COMMENTS TO APPLICANT

We have completed the re-evaluation of the proposed proprietary name, Probuphine, and have concluded that this name is acceptable.

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[3] USAN stem search conducted on February 16, 2016.

[4] POCA search conducted on October 14, 2015.

[5] eDRLS search conducted on February 16, 2016.

## 5 REFERENCES


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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

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

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

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

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/s/

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MILLIE C BRAHMBHATT
02/18/2016

BRENDA V BORDERS-HEMPHILL
02/18/2016

**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:** | December 8, 2015 |
| **Application Type and Number:** | NDA 204442 |
| **Product Name and Strength:** | Probuphine (buprenorphine HCl) implant<br>80 mg implant |
| **Product Type:** | Single ingredient |
| **Rx or OTC:** | Rx |
| **Applicant/Sponsor Name:** | Titan Pharmaceuticals, Inc. |
| **Panorama #:** | 2015-1601445 |
| **DMEPA Primary Reviewer:** | Millie Shah, PharmD, BCPS |
| **DMEPA Team Leader:** | Vicky Borders-Hemphill, PharmD |

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Probuphine, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

## 1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Probuphine on November 15, 2012. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Probuphine acceptable in OSE Review #2012-2724[1], dated February 11, 2013.

Given the time that has elapsed, the Applicant submitted the name, Probuphine, for review on September 30, 2015.

## 1.2 PRODUCT INFORMATION

The following product information is provided in the September 30, 2015 proprietary name submission.

- Intended Pronunciation: pro-bu′-feen
- Active Ingredient: buprenorphine hydrochloride
- Indication of Use: maintenance treatment of opioid dependence
- Route of Administration: subdermal
- Dosage Form: implant
- Strength: 80 mg
- Dose and Frequency: 4 implants inserted subdermally once, and then removed after 6 months. Therapy may continue after 6 months with insertion of new implants
- How Supplied: One Probuphine carton consists of four individually packaged sterile implants. Each implant is 26 mm in length and 2.5 mm in diameter and contains 80 mg of buprenorphine. Each package contains the four-pouched implants and one sterile, disposable applicator packaged in a (b) (4) pouch.
- Storage/Container Closure System: Store PROBUPHINE at 20 to 25°C (68 to 77°F); excursions permitted at 15 to 30°C (59-86°F) [see USP Controlled Room Temperature].

# 2 RESULTS

[1] Borders-Hemphill V. Proprietary Name Review for Probuphine (NDA 204442). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 FEB 11. 32 p. OSE RCM No.: 2012-2724.

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

## 2.1 MISBRANDING ASSESSMENT

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

## 2.2 SAFETY ASSESSMENT

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

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

There is no USAN stem present in the proprietary name[2].

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

The Applicant indicated in their submission that the proposed name, Probuphine, is derived from:

a) Titan's proprietary ProNeura™ long-term subdermal drug delivery technology served as the source for "Pro", the first syllable, and
b) The active substance, buprenorphine, contributed the "bu" and "phine" last two syllables contained in this proposed proprietary name.

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 FDA Name Simulation Studies*

Sixty-eight practitioners participated in DMEPA's prescription studies. Of the 68 practitioners, 40 correctly interpreted the name Probuphine. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

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

In response to the OSE email dated October 8, 2015, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

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

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[3] organized as highly similar, moderately similar, or low similarity for further evaluation.

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[2]USAN stem search conducted on October 14, 2015.

| Table 1. POCA Search Results | Number of Names |
|---|---|
| Highly similar name pair:<br>combined match percentage score ≥70% | 9 |
| Moderately similar name pair:<br>combined match percentage score ≥50% to ≤ 69% | 552 |
| Low similarity name pair:<br>combined match percentage score ≤49% | 0 |

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

Our analysis of the 561 names contained in Table 1 determined 561 names will not pose a risk for confusion as described in Appendices C through H.

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

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on November 23, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on December 7, 2015, they stated no additional concerns with the proposed proprietary name, Probuphine.

## 3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Cristina Makela, OSE project manager, at 301-796-6632.

### 3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 30, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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[3] POCA search conducted on October 14, 2015

## 4 REFERENCES


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

   USAN Stems List contains all the recognized USAN stems.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

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

***Drugs@FDA***

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

***RxNorm***

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

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

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

***Division of Medication Errors Prevention and Analysis proprietary name consultation requests***

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

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

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

## APPENDICES

### Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [4]

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

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

| | Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance. |
|---|---|
| **Y/N** | **Is the proposed name obviously similar in spelling and pronunciation to other names?** |
| | Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products. |
| **Y/N** | **Are there medical and/or coined abbreviations in the proprietary name?** |
| | Proprietary names should not incorporate medical abbreviations (e.g., QD, BID, or others commonly used for prescription communication) or coined abbreviations that have no established meaning. |
| **Y/N** | **Are there inert or inactive ingredients referenced in the proprietary name?** |
| | Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)). |
| **Y/N** | **Does the proprietary name include combinations of active ingredients?** |
| | Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)). |
| **Y/N** | **Is there a United States Adopted Name (USAN) stem in the proprietary name?** |
| | Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem. |
| **Y/N** | **Is this proprietary name used for another product that does not share at least one common active ingredient?** |
| | Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name. |
| **Y/N** | **Is this a proprietary name of a discontinued product?** |
| | Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients. |

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 50% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥50% to ≤ 69%.
- Low similarity: combined match percentage score ≤49%.

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion, which is an area of concern (See Table 3).
- Moderately similar names with overlapping or similar strengths or doses represent an area for concern for FDA. The dosage and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and it can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form, etc.) may be limited when the strength or dose overlaps. We review such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).
- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

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

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

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

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

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

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

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

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

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

| Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair 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 ≥50% to ≤69%).**

| | |
|---|---|
| Step 1 | Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation.<br><br>For single strength products, also consider circumstances where the strength may not be expressed.<br><br>For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components.<br><br>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:<br><br>• 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. |

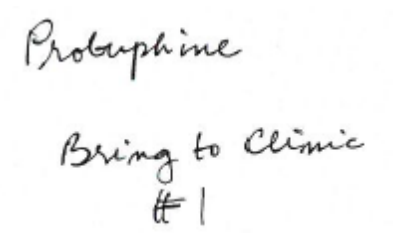
| | | |
|---|---|---|
| | Orthographic Checklist (Y/N to each question)<br>• Do the names begin with different first letters?<br>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.<br>• Are the lengths of the names dissimilar* when 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 ≤49%).**

| |
|---|
| In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation study. In such instances, FDA would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist. |

**Appendix B:** Prescription Simulation Samples and Results

**Figure 1. Probuphine Study (Conducted on October 30, 2015)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>  <br>Outpatient Prescription:<br>  | Probuphine<br>Bring to clinic<br>Dispense number one |

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

242 People Received Study

68 People Responded

Study Name: Probuphine

| Total | 22 | 22 | 24 | |
|---|---|---|---|---|
| **INTERPRETATION** | **OUTPATIENT** | **VOICE** | **INPATIENT** | **TOTAL** |
| PROBUEFENE | 0 | 1 | 0 | 1 |
| PROBUFENE | 0 | 3 | 0 | 3 |
| PROBUFENE OR PROBUPHENE | 0 | 1 | 0 | 1 |
| PROBUFIN | 0 | 1 | 0 | 1 |
| PROBUFINE | 0 | 3 | 0 | 3 |
| PROBUPHEN | 0 | 1 | 0 | 1 |
| PROBUPHENE | 0 | 4 | 11 | 15 |
| PROBUPHINE | 22 | 8 | 9 | 39 |
| PROBUPHINE OR PROBUPHENE | 0 | 0 | 1 | 1 |
| PROBUSPHENE | 0 | 0 | 1 | 1 |
| PROBUSPHINE | 0 | 0 | 1 | 1 |
| ROBUPHINE | 0 | 0 | 1 | 1 |

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

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **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. | Probuphine | 100 | Name subject of this review |
| 2. | Probanthine | 76 | The infixes of this name pair have sufficient orthographic differences. The down-stroke in the letter "p" in Probuphine and the cross-stroke in the letter "t" in Probanthine give the name pair a different shape when scripted.<br>The second syllables (-bu- vs. –ban-) of the name pair sound different.<br>Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 3. | Pro-Banthine | 76 | The infixes of this name pair have sufficient orthographic differences. The down-stroke in the letter "p" in Probuphine and the cross-stroke in the letter "t" in Probanthine give the name pair a different shape when scripted.<br>The second syllables (-bup- vs. –bant-) of the name pair sound different.<br>There is no overlap in strength and/or dose between Probuphine and Pro-Banthine (available in 7.5 mg and 15 mg tablets and dosed 15 mg before meals and at bedtime). |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **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.** |
|---|---|---|---|
| 4. | Promazine | 76 | The infixes of this name pair have sufficient orthographic differences. The upstroke in the letter "b", down-stroke in the letter "p", and upstroke in the letter "h" in Probuphine give the name pair a different shape when scripted.<br>The second syllables (-bu- vs. –ma-) of the name pair sound different.<br>Brand discontinued with no generic equivalent available. ANDA 084510 withdrawn FR effective 10/19/1998. |
| 5. | Prepadine | 72 | The infixes and suffixes of this name pair have sufficient orthographic differences. The location of the down-stroke in the letter "p" in Prepadine and the upstroke of the letter "b" in Probuphine in the infix along with the upstroke of the letter "d" in Prepadine and the location of the down-stroke of the letter "p" in Probuphine in the suffix give the name pair a different shape when scripted.<br>The second (-bu- vs. –pa-) and last (-phine vs. –dine) syllables of the name pair sound different.<br>Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **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.** |
|---|---|---|---|
| 6. | Propine | 71 | The infixes and suffixes of this name pair have sufficient orthographic differences. The upstroke in the letter "b" and "h" in Probuphine gives the name pair a different shape when scripted. Propine has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>Probuphine has an extra syllable.<br>There is no overlap in dose between Probuphine and Propine (dosed 1 drop in affected eye every 12 hours). |
| 7. | Prostin E2 | 71 | The infixes and suffixes of this name pair have sufficient orthographic differences. The down-stroke in the letter "p" and the upstroke in the letter "h" in Probuphine and the cross-stroke in the letter "t" in Prostin E2 give the name pair a different shape when scripted. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables (-phine vs. –stin) of this name pair sound different.<br>There is no overlap in dose between Probuphine and Prostin E2 (dosed 1 suppository vaginally once). |
| 8. | Pramoxine | 70 | The infixes of this name pair have sufficient orthographic differences. The upstroke in the letter "b" and downstroke in the letter "p" in Probuphine give the name pair a different shape when scripted.<br>The second syllables (-bup- vs. –mox-) of this name sound different.<br>There is no overlap in dose between Probuphine and Pramoxine (dose is to apply rectally 2 to 3 times daily). |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | 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. |
|---|---|---|---|
| 9. | Primazine | 70 | The infixes of this name pair have sufficient orthographic differences. The upstroke in the letters "b" and "h" and downstroke in the letter "p" in Probuphine give the name pair a different shape when scripted.<br>The second syllables (-bup- vs. –maz-) of this name sound different. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Pramosone | 68 |
| 2. | Proamatine | 68 |
| 3. | Procaine | 67 |
| 4. | Pramine | 64 |
| 5. | Primidone | 62 |
| 6. | Propulsid | 62 |
| 7. | Pyridoxine | 62 |
| 8. | Trobicin | 62 |
| 9. | Prazosin | 61 |
| 10. | Prinzide | 61 |
| 11. | Probampacin | 61 |
| 12. | Pemoline | 60 |
| 13. | Prednisone | 60 |
| 14. | Proketazine | 60 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 15. | Propafenone | 60 |
| 16. | Paroxetine | 58 |
| 17. | Pimozide | 58 |
| 18. | Piperine | 58 |
| 19. | Proloprim | 58 |
| 20. | Promethacon | 57 |
| 21. | Protopam | 57 |
| 22. | Pilocarpine | 56 |
| 23. | Polocaine | 56 |
| 24. | Primaxin | 56 |
| 25. | Procalamine | 56 |
| 26. | Procalamine 3 | 56 |
| 27. | Prolixin | 56 |
| 28. | Predone | 55 |
| 29. | Protopic | 55 |
| 30. | Protriptyline | 55 |
| 31. | Iopromide | 54 |
| 32. | Persantine | 54 |
| 33. | Prometrium | 54 |
| 34. | Propan | 54 |
| 35. | Robaxin | 54 |
| 36. | Rocephin | 54 |
| 37. | Prometh VC | 53 |
| 38. | Protein C | 53 |
| 39. | Diprosone | 52 |
| 40. | Pentazine | 52 |
| 41. | Plasbumin | 52 |
| 42. | Plasbumin-5 | 52 |
| 43. | Pregabalin | 52 |
| 44. | Premarin | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 45. | Prep-Hem | 52 |
| 46. | Prevacid | 52 |
| 47. | Primethasone | 52 |
| 48. | Procyclidine | 52 |
| 49. | Prandin | 51 |
| 50. | Bromocriptine | 50 |
| 51. | Bupropion | 50 |
| 52. | Pamine | 50 |
| 53. | Panglobulin | 50 |
| 54. | Prednisolone | 50 |
| 55. | Procainamide | 50 |
| 56. | P-V-Tussin | 50 |

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

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 1. | Proline | 65 | The infixes and suffixes of this name pair have sufficient orthographic differences. Proline has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine contains an extra syllable. |
| 2. | Privine | 64 | The infixes and suffixes of this name pair have sufficient orthographic differences. Privine has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine contains an extra syllable. |
| 3. | Propoven | 64 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propoven has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. |
| 4. | Bromaline | 63 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 5. | Promethazine | 63 | The infixes and suffixes of this name pair have sufficient orthographic differences. Promethazine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. Promethazine has an extra syllable. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 6. | Premphase | 62 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 7. | Premphase 14/14 | 62 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 8. | Primaquine | 62 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 9. | Propoxyphene | 62 | The infixes of this name pair have sufficient orthographic differences. Propoxyphene has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second syllables of this name pair sound different. |
| 10. | Prudoxin | 62 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prudoxin has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 11. | Provocholine | 61 | The infixes of this name pair have sufficient orthographic differences. Provocholine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second syllables of this name pair sound different. Provocholine has an extra syllable. |
| 12. | Paredrine | 60 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 13. | Perisine | 60 | The prefixes and infixes of this name pair have sufficient orthographic differences. Perisine has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first and second syllables of this name pair sound different. |
| 14. | Pilopine | 60 | The prefixes and infixes of this name pair have sufficient orthographic differences. Pilopine has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first and second syllables of this name pair sound different. |
| 15. | Primatene | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 16. | Probalan | 60 | The suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 17. | Probenecid | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. Probenecid has an extra syllable. |
| 18. | Procarbazine | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences. Procarbazine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. Procarbazine has an extra syllable. |
| 19. | Proleukin | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 20. | Propiomazine | 60 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propiomazine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. Propiomazine has extra syllables. |
| 21. | Prilocaine | 59 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 22. | Procapan | 59 | The infixes and suffixes of this name pair have sufficient orthographic differences. Procapan has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 23. | Predalone 50 | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The second and last syllables of this name pair sound different. |
| 24. | Previfem | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences. Previfem has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 25. | Prochieve | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 26. | Prodrin | 58 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prodrin has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 27. | Podofin | 57 | The infixes and suffixes of this name pair have sufficient orthographic differences. Podofin has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 28. | Polydine | 57 | The prefixes and infixes of this name pair have sufficient orthographic differences. Polydine has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first and second syllables of this name pair sound different. |
| 29. | Prevalite | 57 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 30. | Proquin | 57 | The infixes and suffixes of this name pair have sufficient orthographic differences. Proquin has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 31. | Paracaine | 56 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 32. | Perphenazine | 56 | The prefixes and infixes of this name pair have sufficient orthographic differences. Perphenazine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first and second syllables of this name pair sound different. Perphenazine has an extra syllable. |
| 33. | Pharmadine | 56 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 34. | Prazolamine | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 35. | Proglycem | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 36. | Promacet | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences. Promacet has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 37. | Propade | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propade has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 38. | Propantheline | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propantheline has 13 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. Propantheline has an extra syllable. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 39. | Proparacaine | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences. Proparacaine has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. Proparacaine has an extra syllable. |
| 40. | Protenate | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 41. | Protilase | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 42. | Protuss D | 56 | The infixes and suffixes of this name pair have sufficient orthographic differences. Protuss D has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables of this name pair sound different. |
| 43. | Pertussin | 55 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 44. | Pralidoxime | 55 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 45. | Pred-Phosphate | 55 | The infixes and suffixes of this name pair have sufficient orthographic differences. Pred-Phosphate has 13 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. |
| 46. | Prodium | 55 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prodium has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 47. | Proferrin | 55 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 48. | Pantethine | 54 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 49. | Peroxin A | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences. Peroxin A has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted. If included, the modifier adds orthographic and phonetic differentiation.<br>The first and last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 50. | Peroxin A 10 | 54 | The prefixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first and last syllables of this name pair sound different. |
| 51. | Plenamine | 54 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 52. | Povidone | 54 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Povidone has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first, second, and last syllables of this name pair sound different. |
| 53. | Precise | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Precise has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 54. | Pred Forte | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. |
| 55. | Pregnitude | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 56. | Prepopik | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prepopik has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 57. | Privigen | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Privigen has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 58. | Procomycin | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 59. | Profen | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Profen has 6 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 60. | Prolastin | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 61. | Prometh Plain | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prometh Plain has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The second and last syllables of this name pair sound different. |
| 62. | Promethegan | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. Promethegan has an extra syllable. |
| 63. | Propecia | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propecia has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 64. | Propofol | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propofol has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 65. | Proprinal | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 66. | Robaxin-750 | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The second and last syllables of this name pair sound different. |
| 67. | Robitussin | 54 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 68. | Papaverine | 53 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 69. | Pontocaine | 53 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 70. | Pramlintide | 53 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 71. | (b) (4)*** | 53 | (b) (4) |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 72. | Puroxcin | 53 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Puroxin has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first, second, and last syllables of this name pair sound different. |
| 73. | Pyrophosphate | 53 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Pyrophosphate has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first, second, and last syllables of this name pair sound different. Pyrophosphate has an extra syllable. |
| 74. | Aprotinin | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The third and last syllables of this name pair sound different. Aprotinin has an extra syllable. |
| 75. | Norethin 1/35e-21 | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |
| 76. | Norethin 1/35e-28 | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 77. | Parcaine | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Parcaine has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. |
| 78. | Pentazocine | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. Pentazocine has an extra syllable. |
| 79. | Phenazine 50 | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |
| 80. | Phenazine-35 | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |
| 81. | Plasbumin-20 | 52 | The prefixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |
| 82. | Plasbumin-25 | 52 | The prefixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 83. | Poly-Histine | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. Poly-Histine has an extra syllable. |
| 84. | Pre-Pen | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Pre-Pen has 6 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 85. | Prevident | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 86. | Priftin | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Prifitin has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 87. | Progest | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Progest has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |

| No. | **Proposed name: Probuphine**<br>**Established name: buprenorphine HCl**<br>**Dosage form: implant**<br>**Strength(s): 80 mg**<br>**Usual Dose: 4 implants subdermally once; remove after 6 months** | **POCA Score (%)** | **Prevention of Failure Mode**<br>**In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names** |
|---|---|---|---|
| 88. | Prohance | 52 | The suffixes of this name pair have sufficient orthographic differences. Prohance has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 89. | Promacot | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Promacot has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 90. | Promolaxin | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. Promolaxin has an extra syllable. |
| 91. | Prostascint | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 92. | Protex D | 52 | The infixes and suffixes of this name pair have sufficient orthographic differences. Protex D has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 93. | Pseudoephedrine | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Pseudoephedrine has 15 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first, second, and last syllables of this name pair sound different. Pseudoephedrine has extra syllables. |
| 94. | Pseudofen | 52 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 95. | Robafen | 52 | The suffixes of this name pair have sufficient orthographic differences. Robafen has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The first syllables of this name pair sound different. |
| 96. | Poly-Tussin | 51 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. Poly-Tussin has an extra syllable. |
| 97. | Proctofoam | 51 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 98. | Provisc | 51 | The infixes and suffixes of this name pair have sufficient orthographic differences. Provisc has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 99. | Robafen PE | 51 | The suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables of this name pair sound different. |
| 100. | Broncho Saline | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Broncho Saline has 13 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first, second, and last syllables of this name pair sound different. Broncho Saline has an extra syllable. |
| 101. | Mycobutin | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 102. | Pediaphen | 50 | The prefixes and infixes of this name pair have sufficient orthographic differences.<br>The first and second syllables of this name pair sound different. |
| 103. | Perigiene | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |
| 104. | Permapen | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 105. | Pneumotussin | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Pneumotussin has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first, second, and last syllables of this name pair sound different. Pneumotussin has an extra syllable. |
| 106. | Pneumotussin 2.5 | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Pneumotussin has 12 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted. If included, the modifier adds orthographic and phonetic differentiation.<br>The first, second, and last syllables of this name pair sound different. Pneumotussin has an extra syllable. |
| 107. | Polymycin | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences.<br>The first, second, and last syllables of this name pair sound different. Polymycin has an extra syllable. |
| 108. | Praxbind*** | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. Praxbind has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 109. | Predicort-50 | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The second and last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 110. | Proctozone-H | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The second and last syllables of this name pair sound different. |
| 111. | Proctozone-P | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The second and last syllables of this name pair sound different. |
| 112. | Proderm | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. Proderm has 7 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 113. | Propagest | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The second and last syllables of this name pair sound different. |
| 114. | Propolis | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. Propolis has 8 letters, whereas Probuphine has 10 letters, giving it a longer length when scripted.<br>The second and last syllables of this name pair sound different. |
| 115. | Prostin VR | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences. If included, the modifier adds orthographic and phonetic differentiation.<br>The last syllables of this name pair sound different. |

| No. | Proposed name: Probuphine<br>Established name: buprenorphine HCl<br>Dosage form: implant<br>Strength(s): 80 mg<br>Usual Dose: 4 implants subdermally once; remove after 6 months | POCA Score (%) | Prevention of Failure Mode<br>In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names |
|---|---|---|---|
| 116. | (b) (4) *** | 50 | (b) (4) |
| 117. | Provenge | 50 | The infixes and suffixes of this name pair have sufficient orthographic differences.<br>The last syllables of this name pair sound different. Probuphine has an extra syllable. |
| 118. | Pyrimethamine | 50 | The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. Pyrimethamine has 13 letters, whereas Probuphine has 10 letters, giving it a shorter length when scripted.<br>The first, second, and last syllables of this name pair sound different. Pyrimethamine has extra syllables. |

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

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Not applicable | |

**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 |
|---|---|---|---|

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 1. | Prop-A-Tane | 69 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 2. | Prophene 65 | 69 | Brand discontinued with no generic equivalent available. ANDA 083538 withdrawn FR effective 09/06/1995. |
| 3. | Progabide | 67 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 4. | Proflavine | 66 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 5. | Propiverine | 66 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 6. | Proglumide | 65 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 7. | Bromuphed | 64 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 8. | Propylene | 64 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 9. | Protropin | 64 | Brand discontinued with no generic equivalent available. NDA 019107 withdrawn FR effective 06/16/2006. |
| 10. | Presamine | 63 | Brand discontinued with no generic equivalent available. NDA 011836 withdrawn FR effective 11/26/1990. |
| 11. | Bromine | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 12. | Prepodyne | 62 | Veterinary product |
| 13. | Prezatide | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 14. | Propamidine | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 15. | Propane | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 16. | Protamone | 62 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 17. | Pirenoxine | 61 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 18. | Predamide | 61 | Brand discontinued with no generic equivalent available. ANDA 088059 withdrawn FR effective 06/21/2000. |
| 19. | Bromhexine | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 20. | Pributazone | 60 | Veterinary product |
| 21. | Probucol | 60 | Brand discontinued with no generic equivalent available. NDA 017535 withdrawn FR effective 06/04/2004. |
| 22. | Prolintane | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 23. | Proxyphylline | 60 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 24. | Povidine | 59 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 25. | Pramiverine | 59 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 26. | Priscoline | 59 | Brand discontinued with no generic equivalent available. NDA 006403 withdrawn FR effective 06/18/2009. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 27. | Propicillin | 59 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 28. | Prostaphlin | 59 | Brand discontinued with no generic equivalent available. NDA 050194 withdrawn FR effective 09/29/1995. |
| 29. | Bromaphedrine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 30. | Paludrine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 31. | Paromycin | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 32. | Perazine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 33. | Piprozoline | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 34. | Pirenzepine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 35. | Pripsen | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 36. | Pro Dine 5000c | 58 | Veterinary product |
| 37. | Profenamine | 58 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 38. | (b) (4) *** | 58 | (b) (4) |
| 39. | Promectin | 58 | Veterinary product |
| 40. | Propacet | 58 | Brand discontinued with no generic equivalent available. ANDA 070107 withdrawn FR effective 01/22/1999. |
| 41. | Propacet 100 | 58 | Brand discontinued with no generic equivalent available. ANDA 070107 withdrawn FR effective 01/22/1999. |
| 42. | Partobulin | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 43. | Pro 12 Mousse | 57 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 44. | Proben-C | 57 | Brand discontinued with no generic equivalent available. ANDA 085552 withdrawn FR effective 01/06/1992. |
| 45. | Plus White | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 46. | Prajmaline | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 47. | Preludin | 56 | Brand discontinued with no generic equivalent available. NDA 011752 withdrawn FR effective 09/22/1999. |
| 48. | Prepulsid | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 49. | Propinox | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 50. | Propionate | 56 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 51. | Isobutane | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 52. | Pergolide | 55 | Veterinary product |
| 53. | Pizotyline | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 54. | Prednimustine | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 55. | Prothiaden | 55 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 56. | Palmatine | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 57. | Papa-Deine #3 | 54 | Brand discontinued with no generic equivalent available. ANDA 088037 withdrawn FR effective 03/13/1991. |
| 58. | Papa-Deine #4 | 54 | Brand discontinued with no generic equivalent available. ANDA 088037 withdrawn FR effective 03/13/1991. |
| 59. | Paradione | 54 | Brand discontinued with no generic equivalent available. NDA 006800 withdrawn FR effective 06/04/2004. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 60. | Podophyllin | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 61. | Prednazoline | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 62. | Pressimmune | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 63. | Prifinium | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 64. | Principen | 54 | Brand discontinued with no generic equivalent available. ANDA 062888 withdrawn FR effective 11/22/2006. |
| 65. | Principen '125' | 54 | Brand discontinued with no generic equivalent available. NDA 050056 withdrawn FR effective 03/02/1994. |
| 66. | Principen '250' | 54 | Brand discontinued with no generic equivalent available. NDA 050056 withdrawn FR effective 03/02/1994. |
| 67. | Principen '500' | 54 | Brand discontinued with no generic equivalent available. ANDA 060127 withdrawn FR effective 11/25/1992. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 68. | Prinize | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 69. | Promestriene | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 70. | Prominol | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 71. | Propa P.H. | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 72. | Propyphenazone | 54 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 73. | Pargyline | 53 | Brand discontinued with no generic equivalent available. NDA 013448 withdrawn FR effective 11/05/1992. |
| 74. | Pertofrane | 53 | Brand discontinued with no generic equivalent available. NDA 013621 withdrawn FR effective 08/05/1996. |
| 75. | Pholedrine | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 76. | Platosin | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 77. | Poldine | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 78. | Preconceive | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 79. | Pricortin | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 80. | Pri-Cortin 50 | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 81. | Proguanil | 53 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 82. | Brovanexine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 83. | Cobutolin | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 84. | Periciazine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 85. | Phenazine | 52 | Brand discontinued with no generic equivalent available. ANDA 086523 withdrawn FR effective 06/22/1999. |
| 86. | Phenazocine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 87. | Pholcodine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 88. | (b) (4) *** | 52 | Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases. |
| 89. | Piperazine | 52 | Veterinary product |
| 90. | Pirarubicin | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 91. | Plegine | 52 | Brand discontinued with no generic equivalent available. NDA 012248 withdrawn FR effective 09/13/2000. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 92. | Predfoam | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 93. | Prenylamine | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 94. | Primperan | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 95. | Progesic | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 96. | (b) (4) *** | 52 | (b) (4) |
| 97. | Prolactin | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 98. | Propentofylline | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 99. | Propionamide | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 100. | Proposed_Name*** | 52 | Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases. |
| 101. | Propyliodone | 52 | Brand discontinued with no generic equivalent available. NDA 009309 withdrawn FR effective 08/05/1996. |
| 102. | Prosaid | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 103. | Protamines | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 104. | Protein S | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 105. | Proteins | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 106. | Protium I.V | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 107. | Prozinc | 52 | Veterinary product |
| 108. | Pur-In Isophane | 52 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 109. | Pyrilamine | 52 | Brand discontinued with no generic equivalent available. ANDA 085231 withdrawn FR effective 04/06/1989. |
| 110. | 1-Propanol | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 111. | Ciproxin | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 112. | Perox-Aid | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 113. | Pipothiazine | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 114. | Piretanide | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 115. | Polygeline | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 116. | Probeta LA | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 117. | Pro-Pen-G | 51 | Veterinary product |
| 118. | Prosed | 51 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 119. | Flopropione | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 120. | Neurotrophin 3 | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 121. | Neurotrophin 4 | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 122. | Pacifene | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 123. | Pagitane | 50 | Brand discontinued with no generic equivalent available. NDA 008951 withdrawn FR effective 08/05/1996. |
| 124. | Pertussin ES | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 125. | Pimafucin | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 126. | Piperocaine | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 127. | (b) (4) *** | 50 | Proposed proprietary name found unacceptable by DMEPA (OSE# (b) (4)). Product approved under new proprietary name Plan B-One Step. |
| 128. | Polaramine | 50 | Brand discontinued with no generic equivalent available. ANDA 086835 withdrawn FR effective 11/18/2003. |
| 129. | Prazepam | 50 | Brand discontinued with no generic equivalent available. ANDA 070427 withdrawn FR effective 1/31/1992. |
| 130. | Predenema | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 131. | Prednesol | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 132. | Prednicen-M | 50 | Brand discontinued with no generic equivalent available. ANDA 084655 withdrawn FR effective 5/22/2000. |
| 133. | Prefrin | 50 | Brand discontinued with no generic equivalent available. NDA 007953 withdrawn FR effective 1/21/1974. |
| 134. | Premique | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 135. | Procof D | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 136. | Promace | 50 | Veterinary product |
| 137. | Promapar | 50 | Brand discontinued with no generic equivalent available. ANDA 084423 withdrawn FR effective 3/13/1991. |
| 138. | Pro-Med | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 139. | Propaderm A | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |

| No. | Name | POCA Score (%) | Failure preventions |
|---|---|---|---|
| 140. | Propaderm C | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 141. | Propoflo | 50 | Veterinary product |
| 142. | Pseudofed | 50 | Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases. |
| 143. | Pyrithione | 50 | Brand discontinued with no generic equivalent available. NDA 017684 withdrawn FR effective 6/04/2004. |
| 144. | Pyrolite | 50 | Brand discontinued with no generic equivalent available. NDA 019412 withdrawn FR effective 3/02/1994. |

**Appendix H:** Names not likely to be confused due to notable spelling, orthographic and phonetic differences.

| No. | Name | POCA Score (%) |
|---|---|---|
| 1. | Riboprine | 67 |
| 2. | Brivudine | 66 |
| 3. | Nalbuphine | 66 |
| 4. | Trophamine | 65 |
| 5. | Trophamine 10 % | 65 |
| 6. | Trophamine 10% | 65 |
| 7. | Trophamine 6 % | 65 |
| 8. | Apomorphine | 64 |
| 9. | Aprodine | 64 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 10. | Bromopride | 64 |
| 11. | Dipropizine | 62 |
| 12. | Trimebutine | 62 |
| 13. | Truphylline | 62 |
| 14. | Bromaphen | 62 |
| 15. | Tronothane | 62 |
| 16. | Buprenorphine | 61 |
| 17. | Brethine | 60 |
| 18. | Budipine | 60 |
| 19. | Carnosine | 60 |
| 20. | Dolophine | 60 |
| 21. | Rogitine | 60 |
| 22. | Bromsite*** | 60 |
| 23. | Aprindine | 59 |
| 24. | (b) (4)*** | 59 |
| 25. | Meprozine | 59 |
| 26. | Clomiphene | 59 |
| 27. | Trocaine | 58 |
| 28. | Tropatepine | 58 |
| 29. | Apresoline | 58 |
| 30. | Atropine | 58 |
| 31. | Atropine-1 | 58 |
| 32. | Brulidine | 58 |
| 33. | Cerubidine | 58 |
| 34. | Clozapine | 58 |
| 35. | Isradipine | 58 |
| 36. | Oprisine | 58 |
| 37. | Terodiline | 58 |
| 38. | Trisudrine | 58 |
| 39. | Tyrosine | 58 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 40. | Tropolone | 58 |
| 41. | Mepirodipine | 57 |
| 42. | Clorophene | 57 |
| 43. | Tromethamine | 56 |
| 44. | Truprofen | 56 |
| 45. | Bamipine | 56 |
| 46. | Carboxine | 56 |
| 47. | Carmustine | 56 |
| 48. | Clonodine | 56 |
| 49. | Dobutamine | 56 |
| 50. | Dramamine | 56 |
| 51. | Felodipine | 56 |
| 52. | Hc Pramoxine | 56 |
| 53. | Lomustine | 56 |
| 54. | Maprotiline | 56 |
| 55. | Morphine | 56 |
| 56. | Robenidine | 56 |
| 57. | Sarcosine | 56 |
| 58. | Tomycine | 56 |
| 59. | Trientine | 56 |
| 60. | X-Trozine | 56 |
| 61. | Bromphen Time | 56 |
| 62. | Rubivite | 56 |
| 63. | Triblide | 56 |
| 64. | Triptone | 56 |
| 65. | Berberine | 55 |
| 66. | Duromine | 55 |
| 67. | Trimazide | 55 |
| 68. | Acepromazine | 54 |
| 69. | Amlodipine | 54 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 70. | Banthine | 54 |
| 71. | Benproperine | 54 |
| 72. | Bornaprine | 54 |
| 73. | Cuprimine | 54 |
| 74. | Donnapine | 54 |
| 75. | Epicriptine | 54 |
| 76. | Flumadine | 54 |
| 77. | Flunazine | 54 |
| 78. | Flupirtine | 54 |
| 79. | Nitrocine | 54 |
| 80. | Obezine | 54 |
| 81. | Regitine | 54 |
| 82. | Rogaine | 54 |
| 83. | Romifidine | 54 |
| 84. | Rondamine | 54 |
| 85. | Supramine | 54 |
| 86. | Terbutaline | 54 |
| 87. | Threonine | 54 |
| 88. | Tisopurine | 54 |
| 89. | Bromphen Dc | 54 |
| 90. | Bromphenex | 54 |
| 91. | Bromphenyl | 54 |
| 92. | Serophene | 54 |
| 93. | (b) (4) *** | 54 |
| 94. | Trepibutone | 54 |
| 95. | Tri Biozene | 54 |
| 96. | Tronolane | 54 |
| 97. | Tryptophan | 54 |
| 98. | Clonidine | 53 |
| 99. | Compazine | 53 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 100. | Creatine | 53 |
| 101. | Deprizine | 53 |
| 102. | Dibucaine | 53 |
| 103. | Epinephrine | 53 |
| 104. | Flamazine | 53 |
| 105. | Lobeline | 53 |
| 106. | Morpholine | 53 |
| 107. | Operidine | 53 |
| 108. | Ornithine | 53 |
| 109. | Reserpine | 53 |
| 110. | Synephrine | 53 |
| 111. | Tri Soxsuprine | 53 |
| 112. | Zotepine | 53 |
| 113. | 2-Pyrrolidone | 53 |
| 114. | Clebopride | 53 |
| 115. | Etoposide | 53 |
| 116. | Trazodone | 53 |
| 117. | Tribenoside | 53 |
| 118. | Troclosene | 53 |
| 119. | Amorolfine | 52 |
| 120. | Atridine | 52 |
| 121. | Berkaprine | 52 |
| 122. | Bleomycine | 52 |
| 123. | Butenafine | 52 |
| 124. | Carmoisine | 52 |
| 125. | Carnitine | 52 |
| 126. | Chirocaine | 52 |
| 127. | Cloverine | 52 |
| 128. | Colchicine | 52 |
| 129. | Cytosine | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 130. | Dezocine | 52 |
| 131. | Dralzine | 52 |
| 132. | Estramustine | 52 |
| 133. | Etravirine | 52 |
| 134. | Fonazine | 52 |
| 135. | Gelofusine | 52 |
| 136. | Isoleucine | 52 |
| 137. | Otrivine | 52 |
| 138. | Replenine | 52 |
| 139. | Ritodrine | 52 |
| 140. | Soloxine | 52 |
| 141. | Sonazine | 52 |
| 142. | Spermidine | 52 |
| 143. | Teramine | 52 |
| 144. | Terbinafine | 52 |
| 145. | Thyroid, Ovine | 52 |
| 146. | Topicaine | 52 |
| 147. | Triadine | 52 |
| 148. | Trialodine | 52 |
| 149. | Tricaine | 52 |
| 150. | Turpentine | 52 |
| 151. | Tyramine | 52 |
| 152. | Apresazide | 52 |
| 153. | Bronitin | 52 |
| 154. | Cobavite | 52 |
| 155. | Epirubicin | 52 |
| 156. | Eprazinone | 52 |
| 157. | Furoxone | 52 |
| 158. | Toremifene | 52 |
| 159. | Tricodene | 52 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 160. | Tru-Micin | 52 |
| 161. | Brimonidine | 51 |
| 162. | Buclizine | 51 |
| 163. | Cloroquine | 51 |
| 164. | Ergonovine | 51 |
| 165. | Guanosine | 51 |
| 166. | Hydrotropine | 51 |
| 167. | Labophylline | 51 |
| 168. | Reboxetine | 51 |
| 169. | Rotigotine | 51 |
| 170. | Tramazoline | 51 |
| 171. | Triprolidine | 51 |
| 172. | Caramiphen | 51 |
| 173. | Hydromorphone | 51 |
| 174. | Nitroprusside | 51 |
| 175. | (b) (4) *** | 51 |
| 176. | Trepoxen-250 | 51 |
| 177. | Triphosphate | 51 |
| 178. | Adenosine | 50 |
| 179. | Afrazine | 50 |
| 180. | Arbutamine | 50 |
| 181. | Biophylline | 50 |
| 182. | Bovadine | 50 |
| 183. | Butacaine | 50 |
| 184. | Carbocaine | 50 |
| 185. | Chorpromazine | 50 |
| 186. | Cladribine | 50 |
| 187. | Diaphine | 50 |
| 188. | Dopamine | 50 |
| 189. | Freamine 6.9 | 50 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 190. | Freamine 8.5% | 50 |
| 191. | Glaucine | 50 |
| 192. | Ibopamine | 50 |
| 193. | Isoxsuprine | 50 |
| 194. | Nimodipine | 50 |
| 195. | (b) (4)*** | 50 |
| 196. | Spermine | 50 |
| 197. | Stavudine | 50 |
| 198. | Suphedrine | 50 |
| 199. | Tetrasine | 50 |
| 200. | (b) (4)*** | 50 |
| 201. | Breonesin | 50 |
| 202. | Bromide Ion | 50 |
| 203. | Bromph Dm | 50 |
| 204. | Capozide | 50 |
| 205. | Capozide 25/15 | 50 |
| 206. | Capozide 25/25 | 50 |
| 207. | Capozide 50/15 | 50 |
| 208. | Capozide 50/25 | 50 |
| 209. | Crospovidone | 50 |
| 210. | Durapatite | 50 |
| 211. | Ferro-Time | 50 |
| 212. | Flumezide | 50 |
| 213. | Fluothane | 50 |
| 214. | Glyburide | 50 |
| 215. | Granocyte-13 | 50 |
| 216. | Granocyte-34 | 50 |
| 217. | Kebuzone | 50 |
| 218. | Nitro-Time | 50 |
| 219. | Rauzide | 50 |

| No. | Name | POCA Score (%) |
|---|---|---|
| 220. | Sebutone | 50 |
| 221. | Terazosin | 50 |
| 222. | Theroxide | 50 |
| 223. | Tobrasone | 50 |
| 224. | Trandide | 50 |
| 225. | Tranxene | 50 |
| 226. | Trenbolone | 50 |
| 227. | Triamonide | 50 |
| 228. | Triamonide 40 | 50 |
| 229. | Tridione | 50 |
| 230. | Triposed | 50 |
| 231. | Triptifed | 50 |
| 232. | Tropicamide | 50 |
| 233. | Trospium | 50 |
| 234. | Trypsin | 50 |

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

| No. | Name |
|---|---|
| 1. | Not Applicable |

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/s/

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MILLIE C BRAHMBHATT
12/08/2015

BRENDA V BORDERS-HEMPHILL
12/08/2015

**Department of Health and Human Services**
**Public Health Service**
**Food and Drug Administration**
**Center for Drug Evaluation and Research**
**Office of Surveillance and Epidemiology**
**Office of Medication Error Prevention and Risk Management**

# Proprietary Name Review

| | |
|---|---|
| Date: | February 11, 2013 |
| Reviewer: | Vicky Borders-Hemphill, Pharm.D.<br>Division of Medication Error Prevention and Analysis |
| Team Leader: | Jamie Wilkins Parker, Pharm.D.<br>Division of Medication Error Prevention and Analysis |
| Division Director: | Carol Holquist, RPh<br>Division of Medication Error Prevention and Analysis |
| Drug Name and Strength: | Probuphine (buprenorphine hydrochloride and ethylene vinyl acetate) 80 mg implant |
| Application Type/Number: | NDA 204442 |
| Applicant/Sponsor: | Titan Pharmaceuticals Inc. |
| OSE RCM #: | 2012-2724 |

*** This document contains proprietary and confidential information that should not be released to the public.***

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# 1 INTRODUCTION

This review evaluates the proposed proprietary name, Probuphine, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively.

## 1.1 PRODUCT INFORMATION

The following product information is provided in the November 15, 2012 proprietary name submission.

- Active Ingredient: buprenorphine hydrochloride
- Established name: buprenorphine implant
- Indication of Use: for the maintenance treatment of opioid dependence
- Route of Administration: inserted subdermally at the inner side of the upper arm about 8-10 cm (3-4 inches) above the medial epicondyle of the humerus
- Dosage Form:
    - Subdermal Implant [a sterile, single, off-white, soft, flexible, ethylene vinyl acetate (EVA) implant]
    - Implant size: rod shaped 26 mm in length and 2.5 mm in diameter
- Strength: each implant contains 80 mg of buprenorphine
- Dose and Frequency:
    - 4 implants inserted every 6 months (alternating arms) initiated after at least 3 days of buprenorphine sublingual tablet (Subutex) titration to a daily dose range of 12-16 mg; SL buprenorphine to be discontinued 12 hrs to 24 hrs prior to the insertion of the implant to avoid potential overdose. Patients requiring > three days per week of supplemental SL buprenorphine for two consecutive weeks or eight days total over four consecutive weeks are eligible to receive one additional implant at any time after two weeks from the initial insertion date. The 5th implant is to be inserted into the same arm/location as the initial four implants. All implants must be removed within six months of the original four implant insertion date
- How Supplied: two planned configurations:
    - four individually pouched implants in a carton co-packaged with one single sterile disposable applicator or
    - single pouched implant co-packaged with a single sterile disposable applicator
- Storage: 20 to 25°C (68 to 77°F), with excursions permitted to 15 to 30°C (59-86°F) [see USP Controlled Room Temperature
- Container Closure System: laminated foil pouch

## 2 RESULTS

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

### 2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion OPDP determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's promotional assessment of the proposed name.

### 2.2 ASSESSMENT

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

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

The January 16, 2013, search of the United States Adopted Name (USAN) stems did not identify that a USAN stem is present in the proposed proprietary name.

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

The Applicant indicated in their submission that the proposed name, Probuphine, is derived from two sources. Titan's proprietary ProNeura™ long-term subdermal drug delivery technology served as the source for "Pro", the first syllable, and the active substance, buprenorphine, contributed the "bu" and "phine" last two syllables of the proposed proprietary name. This proprietary name is comprised of a multiple words that do 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 FDA Name Simulation Studies*

Eighty-three practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with or appear or sound similar to any currently marketed products. Misinterpretations occurred with expected orthographically and phonetically similar letter strings. See Appendix C for the complete listing of interpretations from the verbal and written prescription studies.

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

DAAAP is aware of the proposed name and has not communicated any concerns relating to the proposed name at this time.

#### *2.2.5 Failure Mode and Effects Analysis of Similar Names*

Appendix B lists possible orthographic and phonetic misinterpretations of the letters appearing in the proposed proprietary name, Probuphine. Table 1 lists the names with orthographic, phonetic, or spelling similarity to the proposed proprietary name, Probuphine identified by the primary reviewer, the Expert Panel Discussion (EPD), other review disciplines, and FDA Name simulation studies.

**Table 1: Collective List of Potentially Similar Names (DMEPA, EPD, Other Disciplines, and FDA Name Simulation Studies)**

| Look Similar | | | | | |
|---|---|---|---|---|---|
| ***Name*** | ***Source*** | ***Name*** | ***Source*** | ***Name*** | ***Source*** |
| Dolophine | FDA | Procetofene | FDA | Protropin | FDA |
| Nalbuphine | FDA | Proctofoam | FDA | (b) (4) | FDA |
| Pralidoxime | FDA | Prolastin-c | FDA | Raloxifene | FDA |
| Previfem | FDA | Proleukin | FDA | Reboxetine | FDA |
| Probampacin | FDA | Proloprim | FDA | Riboflavin | FDA |
| Probanthine | FDA | Prophene 65 | FDA | Robafen | FDA |
| ProBarimin QT | FDA | Prostaphlin | FDA | Rocephin | FDA |
| **Look and Sound Similar** | | | | | |
| ***Name*** | ***Source*** | ***Name*** | ***Source*** | ***Name*** | ***Source*** |
| Buprenorphine | FDA | | | | |

Our analysis of the 22 names contained in Table 1 considered the information obtained in the previous sections along with their product characteristics. We determined 22 names will not pose a risk for confusion as described in Appendices D through E.

### *2.2.6 Communication of DMEPA's Final Decision to Other Disciplines*

DMEPA communicated our findings to DAAAP via e-mail on January 22, 2013. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DAAAP on January 23, 2013, they stated no additional concerns with the proposed proprietary name, Probuphine.

## 3 CONCLUSIONS

The proposed proprietary name, Probuphine, is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Mark Liberatore, OSE project manager, at 301-796-2221.

### 3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Probuphine, and have concluded that this name is acceptable. However, if any of the proposed product characteristics as stated in your November 15, 2012 submission are altered, the name must be resubmitted for review.

Additionally, the proposed proprietary name must be re-reviewed 90 days prior to approval of the NDA. The conclusions upon re-review are subject to change.

## 4 REFERENCES


1. ***Micromedex Integrated Index (http://csi.micromedex.com)***

   Micromedex contains a variety of databases covering pharmacology, therapeutics, toxicology and diagnostics.

2. ***Phonetic and Orthographic Computer Analysis (POCA)***

   POCA is a database which was created for the Division of Medication Error Prevention and Analysis, FDA. As part of the name similarity assessment, proposed names are evaluated via a phonetic/orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists which operates in a similar fashion.

3. ***Drug Facts and Comparisons, online version, St. Louis, MO (http://factsandcomparisons.com)***

   Drug Facts and Comparisons is a compendium organized by therapeutic course; it contains monographs on prescription and OTC drugs, with charts comparing similar products. This database also lists the orphan drugs.

4. ***FDA Document Archiving, Reporting & Regulatory Tracking System [DARRTS]***

   DARRTS is a government database used to organize Applicant and Sponsor submissions as well as to store and organize assignments, reviews, and communications from the review divisions.

5. ***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.

6. ***Drugs@FDA (http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm)***

   Drugs@FDA contains most of the drug products approved 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, generic drugs, therapeutic biological products, prescription and over-the-counter human drugs and discontinued drugs and “Chemical Type 6” approvals.

7. ***U.S. Patent and Trademark Office (http://www.uspto.gov)***

   USPTO provides information regarding patent and trademarks.

8. ***Clinical Pharmacology Online (www.clinicalpharmacology-ip.com)***

   Clinical Pharmacology contains full monographs for the most common drugs in clinical use, plus mini monographs covering investigational, less common, combination, nutraceutical and nutritional products. It also provides a keyword search engine.

9. ***Data provided by Thomson & Thomson's SAEGIS ™ Online Service, available at (www.thomson-thomson.com)***

   The Pharma In-Use Search database contains over 400,000 unique pharmaceutical trademarks and trade names that are used in about 50 countries worldwide. The data is provided under license by IMS HEALTH.

10. ***Natural Medicines Comprehensive Databases (www.naturaldatabase.com)***

    Natural Medicines contains up-to-date clinical data on the natural medicines, herbal medicines, and dietary supplements used in the western world.

11. ***Access Medicine (www.accessmedicine.com)***

    Access Medicine® from McGraw-Hill contains full-text information from approximately 60 titles; it includes tables and references. Among the titles are: Harrison's Principles of Internal Medicine, Basic & Clinical Pharmacology, and Goodman and Gilman's The Pharmacologic Basis of Therapeutics.

12. ***USAN Stems (http://www.ama-assn.org/ama/pub/about-ama/our-people/coalitions-consortiums/united-states-adopted-names-council/naming-guidelines/approved-stems.shtml)***

    USAN Stems List contains all the recognized USAN stems.

13. ***Red Book (www.thomsonhc.com/home/dispatch)***

    Red Book contains prices and product information for prescription, over-the-counter drugs, medical devices, and accessories.

14. ***Lexi-Comp (www.lexi.com)***

    Lexi-Comp is a web-based searchable version of the Drug Information Handbook.

15. ***Medical Abbreviations (www.medilexicon.com)***

    Medical Abbreviations dictionary contains commonly used medical abbreviations and their definitions.

16. ***CVS/Pharmacy (www.CVS.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

17. ***Walgreens (www.walgreens.com)***

    This database contains commonly used over the counter products not usually identified in other databases.

18. ***Rx List (www.rxlist.com)***

    RxList is an online medical resource dedicated to offering detailed and current pharmaceutical information on brand and generic drugs.

19. ***Dogpile (www.dogpile.com)***

    Dogpile is a Metasearch engine that searches multiple search engines including Google, Yahoo! and Bing, and returns the most relevant results to the search.

20. ***Natural Standard (http://www.naturalstandard.com)***

    Natural Standard is a resource that aggregates and synthesizes data on complementary and alternative medicine.

## APPENDICES

### Appendix A

FDA's Proprietary Name Risk Assessment considers the promotional and safety aspects of a proposed proprietary name. The promotional review of the proposed name is conducted by OPDP. OPDP evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. OPDP provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

The safety assessment is conducted by DMEPA. DMEPA staff search a standard set of databases and information sources to identify names that are similar in pronunciation, spelling, and orthographically similar when scripted to the proposed proprietary name. Additionally, 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.). 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. [1]

Following the preliminary screening of the proposed proprietary name, DMEPA gathers to discuss their professional opinions on the safety of the proposed proprietary name. This meeting is commonly referred to the Center for Drug Evaluation and Research (CDER) Expert Panel discussion. DMEPA also considers other aspects of the name that may be misleading from a safety perspective. DMEPA staff conducts a prescription simulation studies using FDA health care professionals. 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. DMEPA bases the overall risk assessment on the findings of a Failure Mode and Effects Analysis (FMEA) of the proprietary name and misleading nature of the proposed proprietary name with a focus on the avoidance of medication errors.

DMEPA uses the clinical expertise of its staff to anticipate the conditions of the clinical setting where the product is likely to be used based on the characteristics of the proposed product. DMEPA considers the product characteristics associated with the proposed product throughout the risk assessment because the product characteristics of the

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

proposed may provide a context for communication of the drug name and ultimately determine the use of the product in the *usual* clinical practice setting.

Typical product characteristics considered when identifying drug names that could potentially be confused with the proposed proprietary name include, but are not limited to; established name of the proposed product, proposed indication of use, dosage form, route of administration, strength, unit of measure, dosage units, recommended dose, typical quantity or volume, frequency of administration, product packaging, storage conditions, patient population, and prescriber population. DMEPA considers how these product characteristics may or may not be present in communicating a product name throughout the medication use system. Because drug name confusion can occur at any point in the medication use process, DMEPA considers the potential for confusion throughout the entire U.S. medication use process, including drug procurement, prescribing and ordering, dispensing, administration, and monitoring the impact of the medication.[2]

The DMEPA considers the spelling of the name, pronunciation of the name when spoken, and appearance of the name when scripted. DMEPA compares the proposed proprietary name with the proprietary and established name of existing and proposed drug products and names currently under review at the FDA. DMEPA compares the pronunciation of the proposed proprietary name with the pronunciation of other drug names because verbal communication of medication names is common in clinical settings. DMEPA examines the phonetic similarity using patterns of speech. If provided, DMEPA will consider the Sponsor's intended pronunciation of the proprietary name. However, DMEPA also considers a variety of pronunciations that could occur in the English language because the Sponsor has little control over how the name will be spoken in clinical practice. The orthographic appearance of the proposed name is evaluated using a number of different handwriting samples. DMEPA applies expertise gained from root-cause analysis of postmarketing medication errors to identify sources of ambiguity within the name that could be introduced when scripting (e.g.,"T" may look like "F," lower case 'a' looks like a lower case 'u,' etc). Additionally, other orthographic attributes that determine the overall appearance of the drug name when scripted (see Table 2 below for details).

[2] Institute of Medicine. Preventing Medication Errors. The National Academies Press: Washington DC. 2006.

**Table 2.** Criteria Used to Identify Drug Names that Look- or Sound-Similar to a Proposed Proprietary Name.

| **Type of Similarity** | **Considerations when Searching the Databases** | | |
|---|---|---|---|
| | *Potential Causes of Drug Name Similarity* | *Attributes Examined to Identify Similar Drug Names* | *Potential Effects* |
| Look-alike | Similar spelling | Identical prefix<br>Identical infix<br>Identical suffix<br>Length of the name<br>Overlapping product characteristics | • Names may appear similar in print or electronic media and lead to drug name confusion in printed or electronic communication<br>• Names may look similar when scripted and lead to drug name confusion in written communication |
| | Orthographic similarity | Similar spelling<br>Length of the name/Similar shape<br>Upstrokes<br>Down strokes<br>Cross-strokes<br>Dotted letters<br>Ambiguity introduced by scripting letters<br>Overlapping product characteristics | • Names may look similar when scripted, and lead to drug name confusion in written communication |
| Sound-alike | Phonetic similarity | Identical prefix<br>Identical infix<br>Identical suffix<br>Number of syllables<br>Stresses<br>Placement of vowel sounds<br>Placement of consonant sounds<br>Overlapping product characteristics | • Names may sound similar when pronounced and lead to drug name confusion in verbal communication |

Lastly, DMEPA considers the potential for the proposed proprietary name to inadvertently function as a source of error for reasons other than name confusion. Post-marketing experience has demonstrated that proprietary names (or components of the proprietary name) can be a source of error in a variety of ways. Consequently, DMEPA considers and evaluates these broader safety implications of the name throughout this assessment and the medication error staff provides additional comments related to the

safety of the proposed proprietary name or product based on professional experience with medication errors.

### 1. Database and Information Sources

DMEPA searches the internet, several standard published drug product reference texts, and FDA databases to identify existing and proposed drug names that may sound-alike or look-alike to the proposed proprietary name. A standard description of the databases used in the searches is provided in the reference section of this review. To complement the process, the DMEPA uses a computerized method of identifying phonetic and orthographic similarity between medication names. The program, Phonetic and Orthographic Computer Analysis (POCA), uses complex algorithms to select a list of names from a database that have some similarity (phonetic, orthographic, or both) to the trademark being evaluated. Lastly, DMEPA reviews the USAN stem list to determine if any USAN stems are present within the proprietary name. The individual findings of multiple safety evaluators are pooled and presented to the CDER Expert Panel. DMEPA also evaluates if there are characteristics included in the composition that may render the name unacceptable from a safety perspective (abbreviation, dosing interval, etc.).

### 2. Expert Panel Discussion

DMEPA gathers gather CDER professional opinions on the safety of the proposed product and discussed the proposed proprietary name (Expert Panel Discussion). The Expert Panel is composed of Division of Medication Errors Prevention (DMEPA) staff and representatives from the Office of Prescription Drug Promotion (OPDP). We also consider input from other review disciplines (OND, ONDQA/OBP). The Expert Panel also discusses potential concerns regarding drug marketing and promotion related to the proposed names.

The primary Safety Evaluator presents the pooled results of the database and information searches to the Expert Panel for consideration. Based on the clinical and professional experiences of the Expert Panel members, the Panel may recommend additional names, additional searches by the primary Safety Evaluator to supplement the pooled results, or general advice to consider when reviewing the proposed proprietary name.

### 3. FDA Prescription Simulation Studies

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

In order to evaluate the potential for misinterpretation of the proposed proprietary name in handwriting and verbal communication of the name, inpatient medication orders and/or outpatient prescriptions are written, each consisting of a combination of marketed and unapproved drug products, including the proposed name. These orders are optically

scanned and one prescription is delivered to a random sample of participating health professionals via e-mail. In addition, a verbal prescription is recorded on voice mail. The voice mail messages are then sent to a random sample of the participating health professionals for their interpretations and review. After receiving either the written or verbal prescription orders, the participants record their interpretations of the orders which are recorded electronically.

### 4. 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.

### 5. Safety Evaluator Risk Assessment of the Proposed Proprietary Name

The primary Safety Evaluator applies his/her individual expertise gained from evaluating medication errors reported to FDA, considers all aspects of the name that may be misleading or confusing, conducts a Failure Mode and Effects Analysis, and provides an overall decision on acceptability dependent on their risk assessment of name confusion. Failure Mode and Effects Analysis (FMEA) is a systematic tool for evaluating a process and identifying where and how it might fail.[3] When applying FMEA to assess the risk of a proposed proprietary name, DMEPA seeks to evaluate the potential for a proposed proprietary name to be confused with another drug name because of name confusion and, thereby, cause errors to occur in the medication use system. FMEA capitalizes on the predictable and preventable nature of medication errors associated with drug name confusion. FMEA allows the Agency to identify the potential for medication errors due to orthographically or phonetically similar drug names prior to approval, where actions to overcome these issues are easier and more effective than remedies available in the post-approval phase.

In order to perform an FMEA of the proposed name, the primary Safety Evaluator must analyze the use of the product at all points in the medication use system. Because the proposed product is has not been marketed, the primary Safety Evaluator anticipates the use of the product in the usual practice settings by considering the clinical and product

[3] Institute for Healthcare Improvement (IHI). Failure Mode and Effects Analysis. Boston. IHI:2004.

characteristics listed in Section 1.2 of this review. The Safety Evaluator then analyzes the proposed proprietary name in the context of the usual practice setting and works to identify potential failure modes and the effects associated with the failure modes.

In the initial stage of the Risk Assessment, the Safety Evaluator compares the proposed proprietary name to all of the names gathered from the above searches, Expert Panel Discussion, and prescription studies, external studies, and identifies potential failure modes by asking:

> ***"Is the proposed proprietary name convincingly similar to another drug name, which may cause practitioners to become confused at any point in the usual practice setting? And are there any components of the name that may function as a source of error beyond sound/look-alike?"***

An affirmative answer indicates a failure mode and represents a potential for the proposed proprietary name to be confused with another proprietary or established drug name because of look- or sound-alike similarity or because of some other component of the name. If the answer to the question is no, the Safety Evaluator is not convinced that the names posses similarity that would cause confusion at any point in the medication use system, thus the name is eliminated from further review.

In the second stage of the Risk Assessment, the primary Safety Evaluator evaluates all potential failure modes to determine the likely *effect* of the drug name confusion, by asking:

> ***"Could the confusion of the drug names conceivably result in medication errors in the usual practice setting?"***

The answer to this question is a central component of the Safety Evaluator's overall risk assessment of the proprietary name. If the Safety Evaluator determines through FMEA that the name similarity would not ultimately be a source of medication errors in the usual practice setting, the primary Safety Evaluator eliminates the name from further analysis. However, if the Safety Evaluator determines through FMEA that the name similarity could ultimately cause medication errors in the usual practice setting, the Safety Evaluator will then recommend the use of an alternate proprietary name.

Moreover, DMEPA will object to the use of proposed proprietary name when the primary Safety Evaluator identifies one or more of the following conditions in the Overall Risk Assessment:

a. OPDP finds the proposed proprietary name misleading from a promotional perspective, and the Review Division concurs with OPDP's findings. The Federal Food, Drug, and Cosmetic Act provides that labeling or advertising can misbrand a product if misleading representations are made or suggested by statement, word, design, device, or any combination thereof, whether through a PROPRIETARY name or otherwise [21 U.S.C 321(n); See also 21 U.S.C. 352(a) & (n)].

b. DMEPA identifies that the proposed proprietary name is misleading because of similarity in spelling or pronunciation to another proprietary or established name of a different drug or ingredient [CFR 201.10.(C)(5)].

c. FMEA identifies the potential for confusion between the proposed proprietary name and other proprietary or established drug name(s), and demonstrates that medication errors are likely to result from the drug name confusion under the conditions of usual clinical practice.

d. The proposed proprietary name contains an USAN (United States Adopted Names) stem.

e. DMEPA identifies a potential source of medication error within the proposed proprietary name. For example, the proprietary name may be misleading or, inadvertently, introduce ambiguity and confusion that leads to errors. Such errors may not necessarily involve confusion between the proposed drug and another drug product but involve a naming characteristic that when incorporated into a proprietary name, may be confusing, misleading, cause or contribute to medication errors.

If DMEPA objects to a proposed proprietary name on the basis that drug name confusion could lead to medication errors, the primary Safety Evaluator uses the FMEA process to identify strategies to reduce the risk of medication errors. DMEPA generally recommends that the Sponsor select an alternative proprietary name and submit the alternate name to the Agency for review. However, in rare instances FMEA may identify plausible strategies that could reduce the risk of medication error of the currently proposed name. In that instance, DMEPA may be able to provide the Sponsor with recommendations that reduce or eliminate the potential for error and, thereby, would render the proposed name acceptable.

In the event that DMEPA objects to the use of the proposed proprietary name, based upon the potential for confusion with another proposed (but not yet approved) proprietary name, DMEPA will provide a contingency objection based on the date of approval. Whichever product, the Agency approves first has the right to use the proprietary name, while DMEPA will recommend that the second product to reach approval seek an alternative name.

The threshold set for objection to the proposed proprietary name may seem low to the Applicant/Sponsor. However, the safety concerns set forth in criteria a through e above are supported either by FDA regulation or by external healthcare authorities, including the Institute of Medicine (IOM), World Health Organization (WHO), the Joint Commission, and the Institute for Safe Medication Practices (ISMP). These organizations have examined medication errors resulting from look- or sound-alike drug names, confusing, or misleading names and called for regulatory authorities to address the issue prior to approval. Additionally, DMEPA contends that the threshold set for the Proprietary Name Risk Assessment is reasonable because proprietary drug name confusion is a predictable and preventable source of medication error that, in many instances, the Agency and/or Sponsor can identify and rectify prior to approval to avoid patient harm.

Furthermore, post-marketing experience has demonstrated that medication errors resulting from drug name confusion are notoriously difficult to rectify post-approval. Educational and other post-approval efforts are low-leverage strategies that have had limited effectiveness at alleviating medication errors involving drug name confusion. Sponsors have undertaken higher-leverage strategies, such as drug name changes, in the

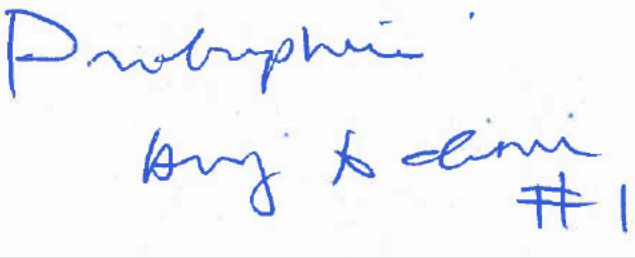
past but at great financial cost to the Sponsor and at the expense of the public welfare, not to mention the Agency's credibility as the authority responsible for approving the error-prone proprietary name. Moreover, even after Sponsors' have changed a product's proprietary name in the post-approval phase, it is difficult to eradicate the original proprietary name from practitioners' vocabulary, and as a result, the Agency has continued to receive reports of drug name confusion long after a name change in some instances. Therefore, DMEPA believes that post-approval efforts at reducing name confusion errors should be reserved for those cases in which the potential for name confusion could not be predicted prior to approval.

**Appendix B:** Letters with Possible Orthographic or Phonetic Misinterpretation

| **Letters in Name Probuphine** | **Scripted May Appear as** | **Spoken May Be Interpreted as** |
|---|---|---|
| Capital 'P' | D | B, F |
| Lower case 'p' | g, j, l, q | B, f |
| Lower case 'r' | s, n, v | --- |
| Lower case 'o" | a, c, e ,u | oh, u |
| Lower case 'b' | l, h, k | p, v, d, f |
| Lower case 'u" | n, y, v, w, Any Vowel | --- |
| Lower case "p" | yn, ys, g, j, l, q, y, ja, jo, x, z | b |
| Lower case "h" | k, b, n, L | --- |
| Lower case 'i' | e, l | y, ee |
| Lower case 'n' | m, u, x, r, h, s | dn, gn, kn, mn, pn |
| Lower case 'e' | a, i, l, o, u,p | any vowel |
| **Letter strings in Name Probuphine** | **Scripted May Appear as** | **Spoken May Be Interpreted as** |
| Pro- | Pra, Pri, Pre, Pru, Dra, Dre, Dri, Dro, Dru, gra, gre, gri, gro, gru, jra, jre, jri, jro, jru, lra, lre, lri, lro, lru, qra, qre, qri, qro, qru | Bra, Bre, Bri, Bro, Bru, Fra, Fre, Fri, Fro, Fru |
| Pr | R | |
| bu | ba, be, bi, la, le, li, lu, ha, he, hi, hu, ka, ke, ki, ku | pu, vu, vue, du, do |
| phine | plune, plane, puine, plure | feen, veen, fine, vine, cee, seen, si |

**Appendix C:** Prescription Simulation Samples and Results

**Figure 1. Probuphine Study (Conducted on December 6, 2012)**

| Handwritten Requisition Medication Order | Verbal Prescription |
|---|---|
| Medication Order:<br>Probuphine 4 implants subdermally | Probuphine<br>Bring to clinic<br>Dispense #1 |
| Outpatient Prescription:<br>  | |

**FDA Prescription Simulation Responses. (Aggregate 1 Rx studies report)**

194 People Received Study
83 People Responded
**Study Name: Probuphine**

| Total | 25 | 29 | 29 | |
|---|---|---|---|---|
| **INTERPRETATION** | **INPATIEN** | **VOICE** | **OUTPATIE** | **TOTAL** |
| ? | 0 | 1 | 0 | 1 |
| BROBUPHEN | 0 | 1 | 0 | 1 |
| BROFUCINE | 0 | 1 | 0 | 1 |
| PRO??? | 0 | 1 | 0 | 1 |
| PROBENPHINE | 2 | 0 | 0 | 2 |
| PROBEPHINE | 1 | 0 | 0 | 1 |
| PROBERFINE | 1 | 0 | 0 | 1 |
| PROBERPHINE | 4 | 0 | 0 | 4 |
| PROBIPHINE | 1 | 0 | 1 | 2 |
| PROBIPHRIN | 0 | 0 | 1 | 1 |
| PROBORPHINE | 0 | 0 | 1 | 1 |
| PROBREPHINE | 0 | 0 | 1 | 1 |
| PROBRIPHINE | 0 | 0 | 5 | 5 |
| PROBRYPHIN | 0 | 0 | 1 | 1 |
| PROBUFEEN | 0 | 1 | 0 | 1 |
| PROBUFEN | 0 | 0 | 1 | 1 |
| PROBUFENE | 0 | 1 | 0 | 1 |
| PROBUFIN | 0 | 1 | 0 | 1 |
| PROBUFINE | 0 | 3 | 0 | 3 |
| PROBUPHENE | 0 | 1 | 0 | 1 |
| PROBUPHIBE | 1 | 0 | 0 | 1 |
| PROBUPHIN | 0 | 0 | 2 | 2 |
| PROBUPHIN INJECTION | 0 | 0 | 1 | 1 |
| PROBUPHINE | 14 | 1 | 7 | 22 |
| PROBUPHINE 4 | 1 | 0 | 0 | 1 |
| PROBUPHINE? | 0 | 0 | 1 | 1 |
| PROBUPHRIN | 0 | 0 | 2 | 2 |
| PROBUPHRINE | 0 | 0 | 5 | 5 |
| PROFUCEE | 0 | 1 | 0 | 1 |
| PROFUCIE | 0 | 1 | 0 | 1 |
| PROFUCINE | 0 | 1 | 0 | 1 |
| PROFUPHINE | 0 | 1 | 0 | 1 |
| PROFUSEE | 0 | 1 | 0 | 1 |
| PROFUSEIN | 0 | 1 | 0 | 1 |
| PROFUSENE | 0 | 1 | 0 | 1 |
| PROFUSI | 0 | 1 | 0 | 1 |
| PROFUSIE | 0 | 1 | 0 | 1 |
| PROFUSINE | 0 | 1 | 0 | 1 |
| PROFUZIE | 0 | 1 | 0 | 1 |
| PROVUCINE | 0 | 2 | 0 | 2 |
| PROVUFINE | 0 | 2 | 0 | 2 |
| PROVUSINE | 0 | 2 | 0 | 2 |

**Appendix D:** Proprietary names not likely to be confused or not used in usual practice settings for the reasons described.

| No. | Proprietary Name | Active Ingredient | Similarity to Probuphine | Failure preventions |
|---|---|---|---|---|
| 1 | Buprenorphine | Active ingredient in Burpenex, Butrans, Suboxone, and Subutex with generic products available **as well as Probuphine*** | Orthographic and Phonetic | The pair have sufficient orthographic differences and phonetic differences |
| 2 | (b) (4) | (b) (4) | (b) (4) | (b) (4) |
| 3 | Previfem | ethinyl estradiol/norgestimate | Orthographic | The pair have sufficient orthographic differences |
| 4 | ProBarimin QT | multivitamin and mutlimineral with iron | Orthographic | The pair have sufficient orthographic differences |
| 5 | Pralidoxime | pralidoxime | Orthographic | The pair have sufficient orthographic differences |
| 6 | Procetofene | related term for fenofibrate | Orthographic | The pair have sufficient orthographic differences |
| 7 | Reboxetine | active ingredient in Vestra | Orthographic | The pair have sufficient orthographic differences |
| 8 | Riboflavin | Vitamin B2 | Orthographic | The pair have sufficient orthographic differences |
| 9 | Prostaphlin | Oxacillin | Orthographic | International brand |

| | | | | |
|---|---|---|---|---|
| | | | | name used in Czech Republic, Estonia, Lithuania, and Slovakia |
| **10** | Protropin | Somatrem | Orthographic | Product withdrawn FR effective 6/16/2006 |
| **11** | Prophene 65 | propoxyphene hydrochloride | Orthographic | Product withdrawn FR effective 9/6/1995; generics discontinued |

**Appendix E:** Risk of medication errors due to product confusion minimized by dissimilarity of names and/or use in clinical practice for reasons described.

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Probanthine (Propantheline Bromide)<br>Strength: 15 mg tablets<br>Dosage form: tablets<br>Dose: 1 tablet 30 min before meals and 2 tablets at bedtime<br>Route of Administration: oral | <u>Orthographic similarity:</u><br>Both names begin with letter string "Prob" and end with the letter string “hine” | <u>Orthographic differences:</u><br>Probuphine has a fewer letters in its infix and suffix compared to Probanthine. Thus, Probanthine appears more orthographically elongated than Probuphine. Probuphine has a downstroke letter “p” and Probanthine has an upstroke letter “t’ in the suffix.<br>The letter string "buphine" is not orthographically similar to the letter string "banthine" when scripted.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine 320 mg or 4 implants vs. Probanthine 15 mg or 30 mg<br>Frequency: Probuphine every 6 months vs. Probanthine with meals and at bedtime |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Proleukin (Aldesleukin)<br>Strength: 22 million international units (1.3 mg)<br>Dosage form: lyophilized powder for reconstitution<br>Dose: 600,000 international units/kg (0.037 mg/kg) every 8 hours infused over 15 minutes for a maximum of 14 doses followed by 9 days off and another 14 doses; dose for 70 kg patient is 42 million international units (2.59 mg)<br>Route of Administration: Intravenous infusion | <u>Orthographic similarity:</u><br>Both names begin with letter string "Pro", and the letter 'b' in Probuphine appears orthographically similar to the letter 'l' in Proleukin when scripted. | <u>Orthographic differences:</u><br>The letter string "uphine" is not orthographically similar to the letter string "eukin" when scripted. Probuphine has a downstroke letter 'p' vs. Probanthine has a cross stroke "t" in its suffix.<br><br><u>Product characteristic differences:</u><br>Strength and unit of measure: Probuphine 80 mg vs. Proleukin 22 million international units or 1.3 mg<br>Dose: Probuphine 320 mg or 4 implants vs. Proleukin weight based dosing (600,000 international units/kg or 0.037 mg/kg)<br>Frequency: Probuphine every 6 months vs. Proleukin every 8 hours |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Prolastin-C (Alpha1-Proteinase Inhibitor)<br>Strength: 1000 mg<br>Dosage form: injection powder for reconstitution<br>Dose: 60 mg/kg once weekly (dose for 70 kg patient is 4200 mg)<br>Route of Administration: Intravenously | <u>Orthographic similarity:</u><br>Both names begin with letter string "Pro", and the letter string 'b' in Probuphine appears orthographically similar to the letter 'l' in Prolastin-C when scripted. | <u>Orthographic differences:</u><br>The letter string "uphine" appears more orthographically elongated and is not similar to the letter string "astin" when scripted. Probuphine has a down stroke letter 'p' vs. Prolastin has a cross stroke "t" in its suffix.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine 320 mg or 4 implants vs. Prolastin-C weight based dosing (60 mg/kg)<br>Frequency: Probuphine every 6 months vs. Prolastin-C once weekly |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Proloprim (Trimethoprim)<br>Strength: 100 mg and 200 mg<br>Dosage form: tablet<br>Dose: 100 mg every 12 hours or 200 mg every 24 hrs for 10 days<br>Route of Administration: Oral | <u>Orthographic similarity:</u><br>Both names begin with letter string "Pro", and the letter string 'bu' in Probuphine appears orthographically similar to the letter string 'lo' in Proloprim when scripted. The suffix of both names contains a downstroke letter 'p'. | <u>Orthographic differences:</u><br>The letter string "hine" has an upstroke letter 'h' vs. no upstroke letters in the letter string "rim".<br><br><u>Product characteristic differences:</u><br>Strength: single strength Probuphine 80 mg vs. multiple strength Proloprim (100 mg and 200 mg) which has to be stated on the prescription.<br>Dose: Probuphine 320 mg or 4 implants vs. Proloprim 100 mg or 200 mg<br>Frequency: Probuphine every 6 months vs. Proloprim every 12 hours or every 24 hours |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Dolophine (methadone)<br>Strength: 5 mg and 10 mg and<br>10 mg /mL<br>Dosage form: tablets and injection Dose:<br>For Pain opioid non-tolerant oral and parenteral 2.5 mg to 10 mg every 8 to 12 hours; For detoxification oral 15 mg to 30 mg once not to exceed 40 mg/day initially then 5 mg to 10 mg as needed every 2 hours to 4 hours; parenteral (inpatient only) use a 2:1 ratio when converting from oral to parenteral; maintenance oral 40 mg daily in divided doses to 80 mg to 120 mg daily in divided doses<br>Route of Administration: Oral and intravenous, intramuscular, and subcutaneous | <u>Orthographic similarity:</u><br>Both names begin with letters that may be similarly scripted (P vs. D). The letter string 'bu' in Probuphine appears orthographically similar to the letter string 'lo' in Dolophine when scripted. Both names have the suffix "phine". | <u>Product characteristic differences:</u><br>Strength: single strength Probuphine 80 mg vs. multiple strength Dolophine (5 mg, 10 mg, and 10 mg/mL) which has to be stated on the prescription<br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. Dolophine has interpatient variability and dose must be expressed<br>Frequency: Probuphine every 6 months vs. Dolophine every 8 hours to 12 hours (pain) or every 2 hours to 4 hours (detoxification)<br>Route of Administration: Probuphine has a single route (intradermal) vs. Dolophine has multiple routes (oral and intravenous, intramuscular, and subcutaneous) |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Raloxifene (active ingredient in Evista; generic tentative approval)<br>Strength: 60 mg<br>Dosage form: tablet<br>Dose: 60 mg once daily<br>Route of Administration: Oral | <u>Orthographic similarity:</u><br>The letters "Pr" in Probuphine appear orthographically similar to the letter "R" in Raloxifene when scripted. The letter string 'ob' appears orthographically similar to the letter string 'alo' when scripted.<br>The letter 'f'appears orthographically similar to the letter 'p' when scripted | <u>Orthographic differences:</u><br>The letter string 'uphine', appears orthographically elongated due to neighboring letters 'ph' and thus is not orthographically similar to the letter string "xifene" when scripted.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. Dolophine has interpatient variability and dose must be expressed<br>Frequency: Probuphine every 6 months vs. Dolophine every 8 hours to 12 hours (pain) or every 2 hours to 4 hours (detoxification) |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Rocephin (ceftriaxone)<br>Strength: 500 mg/vial and 1 gram/vial Dosage form: reconstituted solution or powder for injection<br>Dose: 1 gram to 2 grams every 24 hours; Pediatrics 50 to 100 mg/kg every 24 hours (average dose ~1450 mg to 2900 mg for 9 yr old child weighing 29 kg)<br>Route of Administration: Intravenous or intramuscular | <u>Orthographic similarity:</u><br>The letters "Pr" in Probuphine appear orthographically similar to the letter "R" in Rocephin when scripted. | <u>Orthographic differences:</u><br>The letter string "buphine', appears orthographically elongated and has an upstroke letter 'b', thus is not orthographically similar to the letter string 'cephin'.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. Rocephin multiple doses (1 gram or 2 grams) and weight based dosing for pediatrics<br>Frequency: Probuphine every 6 months vs. Rocephin every 24 hours<br>Route of Administration: Probuphine has a single route (intradermal) vs. Rocephin has multiple routes (intravenous and intramuscular) |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Nalbuphine (active ingredient for Nubain with generic products available)<br>Strength: 10 mg/mL<br>Dosage form: solution for injection<br>Dose: 10 mg intramuscular, intravenous, subcutaneous every 3 hours to 6 hours as needed for pain or 0.3 mg/kg to 3 mg/kg intravenous over 10 to 15 minutes for general anesthesia induction (average dose for 70 kg adult ~ 21 mg to 210 mg). Subsequent doses as required are 0.25 to 0.5 mg/kg intravenous (average dose for 70 kg adult ~ 17.5 mg to 35 mg).<br>Route of Administration: intramuscular, intravenous, subcutaneous | Orthographic similarity:<br>Both names have the letter string "buphine". | Orthographic differences:<br>The letter string 'Pro' is not orthographically similar to the letter string 'Nal'.<br><br>Product characteristic differences:<br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. Nalbuphine has weight based dosing which must be expressed on the prescription<br>Frequency: Probuphine every 6 months vs. Nalbuphine every 3 hours to 6 hours<br>Route of Administration: Probuphine has a single route (intradermal) vs. Nalbuphine has multiple routes (intravenous, intramuscular, and subcutaneous) |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Proctofoam (hydrocortisone acetate/pramoxine hydrochloride)<br>Strength: 1%<br>Dosage form: aerosol foam<br>Dose: Apply to affected areas 3 to 4 times per day as needed. Or apply to the affected external anorectal area up to 5 times per day; Over-the-Counter product<br>Route of Administration: topical or anorectal | Orthographic similarity:<br>Both names begin with letter string "Pro" and the names overall have the similar shape when scripted<br><br>Product characteristic similarities:<br>Dose/Strength: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants and Proctofoam has one strength which may be omitted on the prescription | Orthographic differences:<br>The letter string 'buphine' is not orthographically similar to the letter string 'ctofoam' since the 'c' in Proctofoam elongates the word before the cross stroke letter "t'.<br><br>Product characteristic differences:<br>Frequency: Probuphine every 6 months vs. Proctofoam 3 to 4 times per day |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Robafen (Guaifenesin)<br>Strength: 100 mg/5 mL<br>Dosage form: syrup<br>Dose: 50 mg to 400 mg every 4 hours. Maximum dosage is 2400 mg/day.<br>Route of Administration: oral | <u>Orthographic similarity:</u><br>The letters "Pr" in Probuphine appear orthographically similar to the letter "R" in Robafen when scripted. | <u>Orthographic differences:</u><br>The letter string "buphine', appears orthographically elongated and has an upstroke letter 'b', thus is not orthographically similar to the letter string 'bafen'.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. Robafen dosing (in mg or mL) must be expressed on the prescription<br>Frequency: Probuphine every 6 months vs. Robafen every 4 hours |

| Proposed Proprietary name: Probuphine (buprenorphine hydrochloride/ethylene vinyl acetate)<br>Strength: 80 mg/implant<br>Dosage form: subdermal implant<br>Dose: Insert 4 implants subdermally every 6 months<br>Route of Administration: intradermal | Failure Mode: Incorrect Product Ordered/ Selected/Dispensed or Administered because of Name confusion<br><br>Causes (could be multiple) | 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 |
|---|---|---|
| Probampacin (ampicillin/ampicillin/trihydrate probenecid)<br>Strength: 3.5 gm/1 gram per bottle<br>Dosage form: powder for oral suspension<br>Dose: A single dose of 3.5 g of ampicillin administered simultaneously with 1 g of probenecid for gonorrhea<br>Route of Administration: oral | <u>Orthographic similarity:</u><br>Both names begin with letter string "Prob". | <u>Orthographic differences:</u><br>The letter string ‘uphine’, which the upstroke letter ‘h’, is not orthographically similar to the letter string ‘ampacin’.<br><br><u>Product characteristic differences:</u><br>Dose: Probuphine milligram dose may be omitted from the prescription or conveyed as 4 implants vs. probampacin dosing must be expressed on the prescription<br>Frequency: Probuphine every 6 months vs. Probampacin one time dose |

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/s/

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BRENDA V BORDERS-HEMPHILL
02/11/2013

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