CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

205054Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	June 12, 2018
Application Type and Number:	NDA 205054
Product Name and Strength:	Lutrate Depot (leuprolide acetate) for depot suspension, (b) (4) 22.5 mg/vial
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Applicant/Sponsor Name:	GP Pharm
Panorama #:	2018-21720701
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lutrate Depot, 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

(b) (4)

Furthermore, we sent an Information Request on March 29, 2018 to clarify the proposed proprietary name because we noted that the proprietary name for this product is presented inconsistently in the container label, carton labeling, and the Prescribing Information as: "Lutrate Depot", (b) (4) "Lutrate Depot 22.5 mg", respectively.[d] The Applicant responded on April 4, 2018 that the "proposed proprietary name is LUTRATE DEPOT, and that the name does not include the product strengths".[e]

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on March 20, 2018[f] and amended on April 4, 2018[e].

- Intended Pronunciation: /lutreɪt Dɪpoʊ/

---

[a] GP PHARM, S.A. Sequence 0004. Submission of Request for Proprietary Name Review for Lutrate Depot - NDA 205054. Sant Quintí de Mediona (Barcelona, Spain): GP PHARM, S.A. 2014 OCT 3. Available from: \\cdsesub1\evsprod\nda205054\0004\m1\us\112-other-corr\request-for-proprietary-name-review-v00.pdf.

[b] Mathew, D. Proprietary Name Review for Lutrate Depot (NDA 205054). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2014 Dec 12. Panorama No. 2014-38516.

[c] Wheeler, C. on behalf of Geoffrey Kim. Complete Response for NDA 205054. Silver Spring (MD): FDA, CDER, OND, DOP1 (US); 2015 May 29. NDA 205054.

[d] Fahnbulleh, F. Information Request for Lutrate Depot (leuprolide acetate) NDA 205054. Silver Spring (MD): FDA, CDER, OSE (US); 2018 MAR 29.

[e] GP PHARM, S.A. Sequence 0045. Amendment of Request for Proprietary Name Review for Lutrate Depot– NDA 205054 - Leuprolide Acetate. Sant Quintí de Mediona (Barcelona, Spain): GP PHARM, S.A. 2018 APR 4. Available from: \\cdsesub1\evsprod\nda205054\0045\m1\us\12-cover-letter\cover-0045.pdf

[f] GP PHARM, S.A. Sequence 0043. Submission of Request for Proprietary Name Review for Lutrate Depot – NDA 205054 - Leuprolide Acetate. Sant Quintí de Mediona (Barcelona, Spain): GP PHARM, S.A. 2018 MAR 20. Available from: \\cdsesub1\evsprod\nda205054\0043\m1\us\118-prop-names\request-for-proprietary-name-review-v01-mar-2018.pdf.

- Active Ingredient: Leuprolide Acetate
- Indication of Use: palliative treatment of advanced prostate cancer
- Route of Administration: Intramuscular
- Dosage Form: For Injection
- Strength: (b) (4) 22.5 mg/vial
- Dose and Frequency:

  (b) (4)

  - 22.5 mg/vial: one injection intramuscularly every 12 weeks
- How Supplied: Supplied as a LUTRATE MIXJECT single-dose delivery system consisting of a vial with a Flip-Off seal containing sterile lyophilized leuprolide acetate microspheres incorporated in a biodegradable polymer, a MIXJECT vial adapter containing the needle, and a pre-filled syringe containing sterile mannitol for injection, USP, 2 mL, pH 4.5 to 7.0.
- Storage: Store at 25ºC (77ºF) excursions permitted to (b) (4) 30°C (b) (4) 86°F).
- Reference Listed Drug: NDA 020517 (b) (4)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) 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[g].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Lutrate Depot, is derived from multiple facets. The first two letters "Lu" comes from Luteinizing hormone, which is the internationally IUPAC name accepted for commonly known leuprolide or leuprorelin (Luteinizing hormone-releasing factor (pig), 6-D-leucine-9-(N-ethyl-L-prolinamide)-10-

[g] USAN stem search conducted on April 17, 2017.

deglycinamide-). "Trate" comes from citrate which is the excipient that plays an important role on the final product. The modifier "Depot" represents the delivery systems used for extended-release dose of drug, usually administered parenterally. This proprietary name is comprised of multiple words that contain the root name "Lutrate" and the modifier "Depot". We further discuss the modifier in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 2, 2018 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Forty-five practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Evaluation of the Modifier, Depot

The Applicant stated that the "Depot" modifier is the pharmaceutical form that consists of delivery system used for extended-release dose of drug, usually administered parenterally.

The modifier "Depot" has been used with other marketed products such as Lupron Depot, Nutropin Depot and Somatuline Depot. These products are also extended-release or long-acting dosage forms administered once or twice monthly. The proposed product is also an extended-release formulation administered once monthly, therefore the use of the modifier appears appropriate.

Additionally, "Depot" is not a drug product on its own and we do not anticipate that the modifier will be written without the root name. Furthermore, omission and oversight of a modifier is cited in literature[h] as a common cause of medication error. If the modifier, "Depot", is omitted, there are no other Lutrate products currently marketed from which the proposed product will need to be distinguished.

Furthermore, we are not aware of any post-marketing errors relating to the misinterpretations of the modifier "Depot." Therefore, we do not find the modifier, Depot, misleading or vulnerable to confusion and find it acceptable for this product.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[i] identified 254 names with the combined score of ≥55% or individual orthographic or phonetic score of ≥70%. We had identified and evaluated some of the names in our previous proprietary name review.[b] We re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the name. We note that none of the

[h] Lesar TS. Prescribing Errors Involving Medication Dosage Forms. J Gen Intern Med. 2002; 17(8): 579-587.

[i] POCA search conducted on April 13, 2018 in version 4.2.

product characteristics have changed and we agree with the findings from our previous review for the names evaluated previously. Therefore, we identified 72 names not previously analyzed. These names are included in Table 1 below.

2.2.7 Names Retrieved for Review Organized by Name Pair Similarity

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

Table 1. Similarity Category	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	71
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 72 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.9 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on June 1, 2018. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DOP1 on June 12, 2018, they stated no additional concerns with the proposed proprietary name, Lutrate Depot.

3 CONCLUSION

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on March 20, 2018, and amended on April 4, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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. [j]

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

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

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

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

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

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

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 3).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[k]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 5) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

---

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

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

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

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

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

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

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

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

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

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

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

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

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

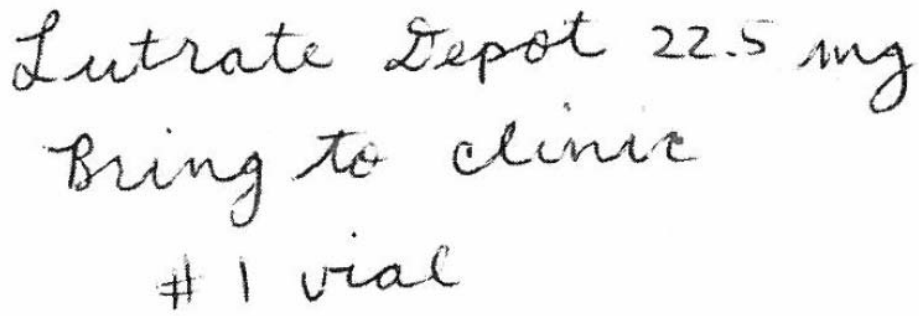
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

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

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Lutrate Depot Study (Conducted on April 13, 2018)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: (b) (4) [redacted] Outpatient Prescription: 	Lutrate Depot 22.5 mg Bring to clinic Dispense number one vial

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

Study Name: Lutrate Depot

As of Date 4/19/2018

299 People Received Study

45 People Responded

Total	**19**	**11**	**15**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
LITRATE DEPOT	0	0	1	1
LUTRAD DEPOT	0	1	0	1
LUTRAIT DEPOT	0	1	0	1
LUTRATE	0	0	1	1
LUTRATE DEPO	0	3	0	3
LUTRATE DEPOT	19	6	12	37
LUTRUTE DEPOT	0	0	1	1

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

No.	**Proposed name:** Lutrate Depot **Established name:** Leuprolide Acetate **Dosage form:** For Injection **Strength(s):** (b) (4) 22.5 mg/vial **Usual Dose:** (b) (4) 22.5 mg intramuscularly every 12 weeks	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Glutarate	80	Name identified in RxNorm database. Glutarate is not a drug. It is an organic compound naturally produced in the body during the metabolism of some amino acids.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
2.	Ala-Tet	62
3.	Durathate	55
4.	Durathate 200	55
5.	Dutrebis	59
6.	Haltran	56
7.	Kaletra	56
8.	Lemtrada	60
9.	Letairis	56
10.	Lunesta	56
11.	Lustra-Ultra	60
12.	Lutathera	59
13.	Rilutek	57
14.	Serpate	56
15.	Ultane	60
16.	Ultra Fresh	55
17.	Ultracare	58
18.	Ultram	62
19.	Ultram ER	60
20.	Ultrasal	56
21.	Zetran	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	**Proposed name:** Lutrate Depot **Established name:** Leuprolide Acetate **Dosage form:** For Injection **Strength(s):** (b) (4) 22.5 mg/vial **Usual Dose:** (b) (4) 22.5 mg intramuscularly every 12 weeks	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
22.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences.
23.	Lactulose	55	This name pair has sufficient orthographic and phonetic differences.
24.	Leustatin	56	This name pair has sufficient orthographic and phonetic differences.
25.	(b) (4)***	62	This name pair has sufficient orthographic and phonetic differences.
26.	(b) (4)***	63	This name pair has sufficient orthographic and phonetic differences. (b) (4)
27.	Ultravist	60	This name pair has sufficient orthographic and phonetic differences.
28.	Ultravist 150	60	This name pair has sufficient orthographic and phonetic differences.
29.	Ultravist 240	60	This name pair has sufficient orthographic and phonetic differences.
30.	Ultravist 300	60	This name pair has sufficient orthographic and phonetic differences.
31.	Ultravist 370	60	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
	N/A	

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

No.	Name	POCA Score (%)	Failure preventions
32.	Acrylate	56	Acrylate is a salt, ester, or conjugate bases of acrylic acid. It is not a finished dosage form.
33.	Altacite	56	International product marketed in United Kingdom, Canada, Ireland, and South Africa.
34.	Altorant	58	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
35.	Altren	65	International product marketed in Belgium.
36.	Aurolate	58	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
37.	Bretylate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Curatrem	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Ethyl Butyrate	57	Product is not a drug. Ethyl acetate is a solvent used in the lacquer industry and is added to various artificial fruit essences.
40.	(b) (4) ***	61	(b) (4)
41.	Glutarol	56	International product marketed in United Kingdom and Ireland.
42.	Hippurate	58	Hippurate is a salt of carboxylic acid. It is not a finished dosage form.
43.	Laureth-11	62	Product is not a drug, but a chemical used in compounding.
44.	Laureth-25	62	Product is not a drug, but a chemical used in compounding.

No.	Name	POCA Score (%)	Failure preventions
45.	Laureth-8	62	Product is not a drug, but a chemical used in compounding.
46.	Lentard	56	Brand discontinued with no generic equivalents available. (b) (4)
47.	(b) (4) ***	60	(b) (4)
48.	Platet	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
49.	Pluratuss	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
50.	Ultra Tears	60	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
51.	Ultralytic	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
52.	Ultralytic 2	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
53.	Url-Tannate	56	Name identified in RxNorm database. Product is deactivated (per Redbook) and no generic equivalents are available.
54.	Ursolate	60	Ursolate is a salt or ester of ursolic acid.
55.	Vetraseb	56	Veterinary product.
56.	(b) (4) ***	64	(b) (4)

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[1].

No.	Name	POCA Score (%)
57.	Aleudrin	58
58.	Allerest	56
59.	Alteplase	55
60.	(b) (4) ***	56
61.	Altoprev	57
62.	(b) (4) ***	60
63.	Altresyn	60
64.	Alu-Tab	57
65.	Elestat	56
66.	Sucrets	56
67.	T-Athlete	56
68.	Telotristat	56
69.	Terra-Vet	56
70.	Valtrex	56
71.	Voltarene	56
72.	Xuret	56

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

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

/s/

TINGTING N GAO
06/13/2018

CHI-MING TU
06/13/2018

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	December 12, 2014
Application Type and Number:	NDA 205054
Product Name and Strength:	Lutrate Depot (Leuprolide Acetate) Injection, (b) (4) 22.5 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	GP-Pharma
Submission Date:	October 3, 2014
Panorama #:	2014-38516
DMEPA Primary Reviewer:	Davis Mathew, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Lutrate Depot, 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 PRODUCT INFORMATION

The following product information is provided in the October 3, 2014 proprietary name submission.

- Intended Pronunciation: ˌlutreɪt Dɪpoʊ
- Active Ingredient: Lueprolide Acetate
- Indication of Use: Palliative treatment of advanced prostate cancer.
- Route of Administration: Intramuscular
- Dosage Form: for Injection
- Strength: (b) (4) 22.5 mg
- Dose and Frequency: (b) (4). 22.5 mg administered intramuscular every 12 weeks.
- How Supplied: One vial, one prefilled syringe, one transfer device including one sterile needle (20 gauge) and a complete prescribing information enclosure.
- Storage: Store at 25°C (77° F) excursions permitted to (b) (4) 30°C (b) (4) 86°F)

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proprietary name[1].

[1]USAN stem search conducted on October 28, 2014.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Lutrate Depot, is derived from multiple facets. The first two letters "Lu" comes from Luteinizing hormone, which is the internationally IUPAC name accepted. "Trate" comes from citrate which is the excipient that plays an important role on the final product. The modifier "Depot" represents the delivery systems used for extended-release dose of drug. This proprietary name is comprised of multiple words that contain the root name "Lutrate" and the modifier "Depot". We further discuss the modifier in Section 2.2.5.

2.2.3 FDA Name Simulation Studies

One hundred and nine (n=109) practitioners participated in DMEPA's prescription studies. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Seventy three (n=73) participants interpreted the name correctly as Lutrate Depot. Four (n=4) additional participants correctly interpreted the root name as Lutrate and omitted the modifier "Depot" in their final responses. Common misinterpretations were the omission of the letter "t" in the modifier "Depot" in the voice study (n=9). 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, November 24, 2014 e-mail, the Division of Oncology (DOP1) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Evaluation of the Modifier, Depot

According to the sponsor, the "Depot" modifier is the pharmaceutical form that consists of delivery system used for extended-release dose of drug, usually administered parenterally.

The modifier "Depot" has been used with other marketed products such as Lupron Depot, Nutropin Depot and Somatuline Depot. These products are also extended-release or long-acting dosage forms administered once or twice monthly. The proposed product is also an extended-release formulation administered once monthly, therefore the use of the modifier appears appropriate. Furthermore, we are not aware of any errors relating to the misinterpretations of the modifier "Depot."

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

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

[2] POCA search conducted on October 28, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	13
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	318
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 331 names contained in Table 1 determined none of the names will pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on November 26, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DOP1 on December 3, 2014, they stated no additional concerns with the proposed proprietary name, Lutrate Depot.

3 CONCLUSIONS

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

If you have further questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 3, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

APPENDICES

Appendix A

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

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

a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. [3]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥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. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: o Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

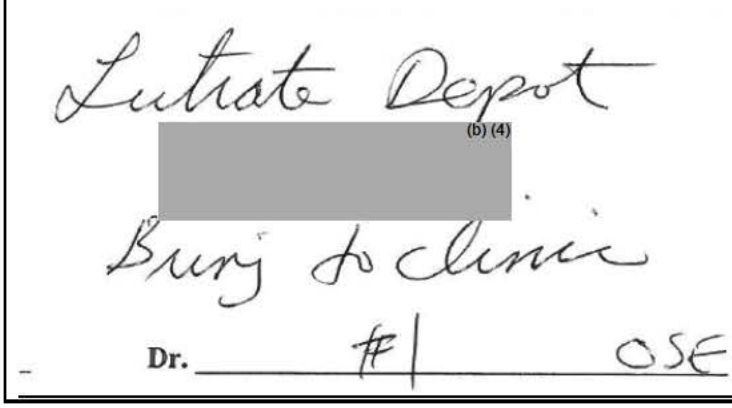
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length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

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤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. Lutrate Depot Study (Conducted on October 24, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Lutrate Depot 22.5mg intramuscular x1 Outpatient Prescription: 	Lutrate Depot (b) (4) Bring to Clinic Dispense #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

258 People Received Study
109 People Responded

Study Name: Lutrate Depot

Total	**34**	**35**	**40**	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
LEUTRATE DEPOT	0	1	0	1
LISTRATE DEPOT	0	0	1	1
LITRATE DEPOT	0	0	1	1
LITRATE DEPOT 22.5	0	0	1	1
LUITRATE DEPOT	0	0	1	1
LURTRATE DEPOT	1	0	0	1
LUTHATE DEPOT	0	0	1	1
LUTISTE DEPOT	1	0	0	1
LUTRAE DEPOT	0	1	0	1
LUTRAIT DEPOT	0	1	0	1
LUTRATE	2	0	2	4
LUTRATE DEPOT	1	0	0	1
LUTRATE DEPAK	0	0	1	1
LUTRATE DEPAT	0	0	1	1
LUTRATE DEPO	0	9	0	9
LUTRATE DEPOT	29	16	28	73
LUTRATE DEPOT.	0	0	1	1
LUTRATE DESPAT	0	0	1	1
LUTRATE DUPO	0	1	0	1
LUTRATE ORPOT	0	0	1	1
LUTRATEDEPOT	0	1	0	1
LUTRAY DEPOT	0	1	0	1
LUTREC DEPO	0	1	0	1
LUTREG DEPO	0	1	0	1
LUTREI DEPO	0	1	0	1
LUTRIN DEPOT	0	1	0	1

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

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	Lutrate	100	International product marketed in Czech Republic and Spain as Lutrate with an established name of Leuprorelin Acetate.
2.	Lupron Depot	78	The infix and suffix of this name pair have sufficient orthographic differences when compared to the root name Lupron. The second syllable of this name pair has phonetic difference when compared to the root name Lupron. We note that despite having similar modifiers there is sufficient differences in orthographic and phonetic characteristics when comparing the root names Lutrate and Lupron.
3.	Citrate	78	Product is not a drug but a derivative of citric acid that is a salt, esters and the polyatomic anion found in solution.
4.	Flurate	74	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair has phonetic difference. Flurate was an ophthalmologic local anesthetic that is no longer marketed.
5.	Laurate	74	Laurate is not a drug. Laurate is a component of Sodium Laurate which is a derivative of Lauric Acid. Sodium Laurate is commonly known as soap.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
6.	Lodrane	74	The suffix of this name pair has sufficient orthographic difference. The second syllable of this name pair has phonetic difference.
7.	Lodrane 24	74	The suffix of this name pair has sufficient orthographic difference. The second syllable of this name pair has phonetic difference.
8.	Lactrase	73	The suffix of this name pair has sufficient orthographic difference. The second syllable of this name pair has phonetic difference. Lactrase is a non-prescription dietary supplement to assist in the digestion of dairy products. It is available as a 250 mg capsule.
9.	Lotusate	72	The second syllable of this name pair has phonetic difference and Lotusate contains an extra syllable compared to the proposed root name Lutrate. Lotusate was available as a 120 mg tablet per Drugs at FDA but unable to find any further product characteristics for this product. The applicant informed the FDA that this product is no longer marketed and has requested the FDA withdraw the approval of the application as of June 11, 1998 per federal register.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
10.	Caltrate	70	The prefix of this name pair has sufficient orthographic difference. The first syllable of this name pair has phonetic difference.
11.	Dilatrate	70	The prefix and infix of this name pair have sufficient orthographic difference. The first and second syllables of this name pair have phonetic difference. Dilatrate contains an extra syllable compared to the proposed root name Lutrate. Dilatrate is only available as a 40 mg capsule however, Lutrate Depot is available in two different strengths which would lead the physician to input a strength next to the name therefore limiting any confusion with Dilatrate.
12.	Foltrate	70	The prefix of this name pair has sufficient orthographic difference. The first syllable of this name pair has phonetic difference.
13.	Lactate	70	The first syllable of this name pair has phonetic difference. Product is not a drug but a conjugate base of lactic acid.

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

No.	Proposed Name	POCA Score (%)
1.	Aclovate	50
2.	Alustra	52
3.	(b) (4) ***	53
4.	Butrans	52
5.	Cafetrate	60
6.	(b) (4) ***	50
7.	Citra pH	52
8.	Clobevate	54
9.	Clofibrate	58
10.	Colgate	50
11.	Contrave	56
12.	Cutivate	62
13.	Cylate	51
14.	Cytra-K	54
15.	Dilatrate-SR	50
16.	Docusate	50
17.	(b) (4) ***	52
18.	Edetate	50
19.	Eloctate	61
20.	(b) (4) ***	66
21.	Estrace	59
22.	Flavoxate	50

No.	Proposed Name	POCA Score (%)
23.	Flutamide	50
24.	Flutex	52
25.	Folnate	52
26.	Glutose	60
27.	Glycate	56
28.	Isoditrate	52
29.	Kutrase	68
30.	Lac-Dose	56
31.	Lacri-lube	53
32.	Lacrisert	51
33.	Lactase	60
34.	Ladropen	52
35.	Lamprene	58
36.	Lapase	58
37.	Latisse	54
38.	Latrix	60
39.	(b) (4) ***	53
40.	(b) (4) ***	56
41.	Leritine	50
42.	Leukeran	56
43.	Levitra	51
44.	Levlite	56
45.	Librax	54

No.	Proposed Name	POCA Score (%)
46.	Librium	50
47.	Lidazone	50
48.	Lidosite	51
49.	Lindane	54
50.	Lingraine	50
51.	Liotrix	56
52.	Lipase	60
53.	Liptruzet	56
54.	Lisuride	58
55.	Lithane	60
56.	(b) (4) ***	52
57.	Lo/Ovral	50
58.	Lo/Ovral-28	50
59.	Locorten	52
60.	Lodrane D	61
61.	Loestrin 21 1.5/30	50
62.	Loestrin 21 1/20	50
63.	(b) (4) ***	50
64.	Loperamide	52
65.	Lopressor	50
66.	Loprox	53
67.	Lopurin	51
68.	Lorabid	52

No.	Proposed Name	POCA Score (%)
69.	Loraz	50
70.	Lorelco	50
71.	Lotrimin	60
72.	Lotrisone	62
73.	Lo-Trol	64
74.	Lotronex	60
75.	LTA Ped	50
76.	(b) (4) ***	57
77.	(b) (4) ***	50
78.	(b) (4) ***	57
79.	Lustra	60
80.	Lustra AF	64
81.	Lutalyse	61
82.	Lutein	61
83.	Lutera	60
84.	Lutetium	50
85.	Lutrelin	66
86.	Lutrepulse	58
87.	Luveris	54
88.	Lyapolate	55
89.	Lypressin	50
90.	Magaldrate	50
91.	Magtrate	60

No.	Proposed Name	POCA Score (%)
92.	Multitrace-4	56
93.	Multitrace-5	56
94.	Neuramate	51
95.	Neutracare	52
96.	Neutracett	60
97.	Neutrahist	52
98.	Neutra-Phos	50
99.	Noritate	50
100.	Norlutate	59
101.	Nutracort	53
102.	Nutralox	50
103.	Nutr-E-Sol	50
104.	Nutrestore	51
105.	Nutrilyte	62
106.	Palmitate	50
107.	Paltrase	60
108.	Parnate	50
109.	Pedtrace-4	53
110.	Predate-50	50
111.	Pre-Sate	50
112.	Rinate	52
113.	R-Tannate	52
114.	Sorbitrate	52

No.	Proposed Name	POCA Score (%)
115.	Stimate	53
116.	Sucralfate	51
117.	Tetra-Ide	56
118.	Tetramed	52
119.	Tolnate	54
120.	Trandate	55
121.	Travase	52
122.	Trilisate	50
123.	Trionate	52
124.	Tussinate	52
125.	Ultra Mide	51
126.	Ultracef	54
127.	Ultrase	69
128.	Ultratag	52
129.	Ultravate	61
130.	Utrona-C	51
131.	Valproate	55
132.	VItraSE	66
133.	Zaltrap	52

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

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
1.	Bock-Arate	55	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair has phonetic difference.
2.	Chlorate	66	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair has phonetic difference.
3.	Dormate	52	The infix of this name pair has sufficient orthographic differences. The first syllable of this name pair has phonetic difference.
4.	Endrate	57	The prefix of this name pair has sufficient orthographic difference. The first syllable of this name pair has phonetic difference.
5.	Ergotrate	62	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have phonetic differences and Ergotrate contains an extra syllable when compared to the proposed root name Lutrate.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
6.	Femtrace	60	The prefix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have phonetic differences.
7.	Ferate	60	The prefix and infix of this name pair have sufficient orthographic differences. The first syllable of this name pair has phonetic difference.
8.	Flo-Pred	56	The prefix, infix and suffix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have phonetic differences.
9.	Kalexate	52	The infix of this name pair has sufficient orthographic difference. The first and second syllables of this name pair have phonetic differences and Kalexate contains an extra syllable when compared to the proposed root name Lutrate.
10.	Larotid	53	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Larotid contains an extra syllable when compared to the proposed root name Lutrate.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
11.	Letrozole	57	The suffix of this name pair has sufficient orthographic difference. The second and third syllables of this name pair have phonetic differences and Letrozole contains an extra syllable when compared to the proposed root name Lutrate.
12.	Leuprolide	58	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Leuprolide contains an extra syllable when compared to the proposed root name Lutrate.
13.	Levoprome	52	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Levoprome contains an extra syllable when compared to the proposed root name Lutrate.
14.	Lipram	56	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic difference.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
15.	Liquimat	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Liquimat contains an extra syllable when compared to the proposed root name Lutrate.
16.	Lithonate	60	The infix of this name pair has sufficient orthographic difference. The second syllable of this name pair has phonetic difference and Lithonate contains an extra syllable when compared to the proposed root name Lutrate.
17.	Lomanate	57	The infix of this name pair has sufficient orthographic difference. The second and third syllables of this name pair have phonetic differences and Lomanate contains an extra syllable when compared to the proposed root name Lutrate.
18.	Lorcet	56	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic difference.
19.	Lorzone	54	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic difference.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
20.	Lotrel	64	The suffix of this name pair has sufficient orthographic differences. The second syllable of this name pair has phonetic differences.
21.	Loxitane	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Loxitane contains an extra syllable when compared to the proposed root name Lutrate.
22.	Ludent	50	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic differences.
23.	Lupron	58	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic difference. This product is no longer manufactured or marketed and was available as a 2.8 mL multi-dose vial.
24.	Luride	63	The infix of this name pair has sufficient orthographic difference. The second syllable of this name pair has phonetic difference.

No.	**Proposed name: Lutrate Depot** **Established name: Leuprolide Acetate** **Dosage form: for Injection** **Strength(s): (b) (4) 22.5 mg** **Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
25.	Luride-SF	50	The infix and suffix of this name pair have sufficient orthographic differences. The second syllable of this name pair has phonetic difference.
26.	Lusedra	50	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair have phonetic differences and Lusedra contains an extra syllable when compared to the proposed root name Lutrate.
27.	Nplate	55	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair have phonetic difference.
28.	Rubratope-57	54	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have phonetic differences and the root name Rubratope consists of an extra syllable when compared to the proposed root name Lutrate.
29.	Rubratope-60	54	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have phonetic differences and the root name Rubratope consists of an extra syllable when compared to the proposed root name Lutrate.

No.	Proposed name: Lutrate Depot Established name: Leuprolide Acetate Dosage form: for Injection Strength(s): (b) (4) 22.5 mg Usual Dose: (b) (4) 22.5 mg Intramuscular every 12 weeks.	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
30.	Ultracet	58	The prefix and suffix of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair have phonetic differences and Ultracet contains an extra syllable when compared to the proposed root name Lutrate.
31.	Ultralente	50	The prefix and infix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair have phonetic differences and Ultralente contains an extra syllable when compared to the proposed root name Lutrate.

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

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	Acetate	50	Product is not a drug but a salt or ester of acetic acid.
2.	Adalate	50	International product marketed in France.
3.	Butamirate	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Butyrate	68	Product is not a drug but is used as part of the name of esters and salts of butyric acid.
5.	Cholate	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
6.	Citravet	57	Veterinary product
7.	Cloburate	64	International product marketed in United kingdom.
8.	Depestrate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
9.	Efloxate	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
10.	Estrate	67	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
11.	Estrumate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
12.	Ethyl Citrate	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Ethyl Nitrate	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Fedrilate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Fenbutrazate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Ferulate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
17.	Folate	52	Product is not a drug but a classification of folic acid derivative.
18.	Formate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Fumarate	64	Product is not a drug but a salt and ester of fumaric acid.

No.	Name	POCA Score (%)	Failure preventions
20.	Fusidate	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Gluceptate	50	Product is not a drug but a 7-carbon carbohydrate derivative.
22.	Gluconate	56	Product is not a drug but a salt and ester of gluconic acid.
23.	Glucuronate	54	Product is not a drug but a salt and ester of glucoronic acid.
24.	Glutamate	62	International product marketed in Japan as Glutamate BCG Vaccine.
25.	Glutaral	52	Product is not a drug but a bactericidal disinfectant.
26.	Glycolate	52	Product is not a drug but a salt or ester of glycolic acid.
27.	Helixate	54	International product marketed in Europe and Canada.
28.	Isotrate	68	International product marketed in Thailand, Ireland and Greece.
29.	Lachesine	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	Lactose	56	Product is not a drug but a disaccharide sugar found in milk products.
31.	Laratrim	52	International product marketed in the United Kingdom.
32.	Latex	53	Product is not a drug but a natural or synthetic aqueous medium used for manufacturing.
33.	Laureth-10	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
34.	Laureth-12	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Laureth-2	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
36.	Laureth-23	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
37.	Laureth-3	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Laureth-30	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
39.	Laureth-4	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Laureth-7	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
41.	Laureth-9	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
42.	Lax-Ease	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
43.	Laxinate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
44.	Lerosett	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Leustat	56	International product marketed in Argentina.
46.	Levulinate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Licorice	56	Product is not a drug but a flavoring agent.
48.	Linoleate	53	Product is not a drug but a salt form of linoleic acid.
49.	Listerine	52	Product is not a drug but an antiseptic mouth wash.
50.	L-lactate	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Looperamide	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
52.	Loperagen	50	International product marketed in United Kingdom.
53.	Lorexane	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
54.	Matmate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
55.	Melitracen	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	Neotrace-4	63	International Product marketed in Hong Kong.
57.	Oleate	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
58.	PEG-12 Laurate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
59.	PEG-4 Laurate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
60.	PEG-8 Laurate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
61.	Picrate	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
62.	(b) (4) ***	54	(b) (4)
63.	Silodrate	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
64.	Simaldrate	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	Sorbate	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
66.	Stearate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
67.	Sucromate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
68.	Sudatrate	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
69.	Tartrate	67	Product is not a drug but a salt or ester of the organic compound tartaric acid.
70.	Taurate	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
71.	Tiludronate	56	Veterinary product
72.	Tramake	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Trynate	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
74.	Ultracept	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Valepotriate	53	Product is not a drug but a class of Iridoid Alkaloids.
76.	Valerate	60	Product is not a drug but a salt or ester of valeric acid.
77.	(b) (4) ***	50	This is a secondary proposed proprietary name and the primary name was withdrawn by the sponsor. Product remains to be classified under its established name (b) (4) If the proposed name (b) (4) *** will be submitted, then we'll perform safety assessment for this name at that time.

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

No.	Name	POCA Score (%)
1.	Almitrine	50
2.	Alocane	50
3.	Altace	52
4.	Alupram	56
5.	Amyl Nitrite	50
6.	Blockade	54
7.	Blu-Kote	60
8.	Butacote	50
9.	Butane	51
10.	Calcitrene	50
11.	Carace	53
12.	Catarase	52
13.	Centrine	50
14.	Cetrotide	50
15.	Chlornade	52
16.	Chlotride	62
17.	Clarite	60
18.	Diurese	50
19.	Doc-Q-Lace	50
20.	Elaprase	62
21.	Ethrane	50
22.	(b) (4) ***	50

No.	Name	POCA Score (%)
23.	Flamrase	60
24.	Flonase	52
25.	Florone	54
26.	Fluotrex	54
27.	Flupirtine	50
28.	Flura-Tab	50
29.	Forane	51
30.	Gladase	50
31.	Glucose	50
32.	Glyburase	51
33.	Glytrin	51
34.	Iloprost	51
35.	Klotrix	54
36.	Mitride	52
37.	Mudrane	58
38.	Nipride	50
39.	Nitrek	50
40.	Nora-Be	50
41.	(b) (4) ***	50
42.	Nydrane	54
43.	Paludrine	50
44.	(b) (4) ***	52
45.	(b) (4) ***	51

No.	Name	POCA Score (%)
46.	(b) (4) ***	52
47.	Sotret	60
48.	Sterane	52
49.	Striant	50
50.	Sucraid	53
51.	Sucrose	58
52.	Sudrine	52
53.	Suprane	63
54.	Supred	50
55.	Supreme	56
56.	(b) (4) ***	50
57.	Tilade	51
58.	(b) (4) ***	51
59.	Trest	51
60.	Tretten	50
61.	Triacet	50
62.	Tridrane	54
63.	Trilyte	56
64.	Tri-Pase	51
65.	Tritec	54
66.	Tri-Tex	52
67.	Trivase	51
68.	Truxade	55

No.	Name	POCA Score (%)
69.	Ubretid	50
70.	Ultresa	50
71.	Ultrex	50
72.	Urese	50
73.	U-Tri-Lone	51
74.	Vetribute	55
75.	Votrient	54
76.	(b) (4) ***	52
77.	Zortress	50

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

/s/

DAVIS MATHEW
12/12/2014

CHI-MING TU
12/12/2014