CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208630Orig1s000

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:	May 25, 2017
Application Type and Number:	NDA 208630
Product Name and Strength:	Gleolan (5-Aminolevulinic Acid Hydrochloride) powder for oral solution 1.5 gram per vial
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	NX Development Corp.
Panorama #:	2017-13964547
DMEPA Primary Reviewer:	Idalia E. Rychlik, PharmD.
DMEPA Team Leader:	Hina Mehta, PhramD.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Gleolan, 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, Gliolan on December 14, 2017. However, the Division of Medication Error Prevention and Analysis (DMEPA) found the name, Gliolan, unacceptable in OSE #2016-11908377 due to the presence of two United States Adopted Name (USAN) stems *–io-* and *Gli.-*.

Thus, the Applicant submitted the name, Gleolan, for review on March 27, 2017.

1.2 PRODUCT INFORMATION

The following product information is provided in the March 27, 2017 proprietary name submission.

- Intended Pronunciation: Glee-ō-lăn
- Active Ingredient: 5-Aminolevulinic Acid Hydrochloride (5-ALA HCL)
- Indication of Use: imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery.
- Route of Administration: Oral
- Dosage Form: Powder for Oral Solution
- Strength: 1.5 gram vial (reconstituted concentration: 30 mg 5-ALA HCL per mL)
- Dose and Frequency: 20 mg/kg 2-4 hours before anesthesia
- How Supplied: 50-ml clear, glass vial
- Storage: 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °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 Medical Imaging Products (DMIP) 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[a].

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Gleolan, was derived from the root "gleo" which is intended to represent glioblastoma. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 10, 2017 e-mail, the Division of Medical Imaging Products (DMIP) 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

Seventy-nine (79) practitioners participated in DMEPA's prescription studies. One inpatient study participant misinterpreted the name Gleolan for the marketed product "Geodon".

Phonetically, the first syllables ("Gle" vs. "Ge") and third syllables ("lan" vs "don") of this name pair provide sufficient phonetic differences. Gleolan and With regard to product characteristics, Gleolan and Geodon differ in terms of strength (*1.5gm vs. 20 mg, 40 mg, 60 mg, 80 mg*), frequency of administration (*once vs. twice daily or as needed [for intramuscular route of administration]*), and dosage form (*capsules and powder for solution for injection vs. powder for oral solution*). Dosing of Gleolan is weight-based (*20 mg/kg*) and dosing overlap with Geodon (*oral: 20mg to 80 mg; intramuscular: 10-40 mg per day*) appears unlikely when the Gleolan dose is expressed in 'mg'.

Additionally, per the applicant's submission dated May 5, 2017, Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Gleolan will only be used by neurosurgeons who have completed a manufacturer mandated training program on the use of fluorescence in surgery. Prescribers of Gleolan must be certified neurosurgeons; in the absence of this certification, the neurosurgeon will not be able to secure Gleolan from the hospital pharmacy for his/her surgical use. (b) (4) [redacted].[b,c] The reconstitution procedure is to be performed by a pharmacist (add 50 mL drinking water and transfer to dosing cup; required total patient specific dose volume is obtained by the pharmacist).

Therefore, in this scenario, due to the above mentioned factors and the phonetic differences, we find this name pair acceptable. We evaluate this name pair in Appendix E.

[a] USAN stem search conducted on (3/27/2017).

[b] NDA 208630. Submission dated May 5, 2017: Cover Letter.

[c] NDA 208630. Submission dated March 3, 2017: Gleolan Prescribing Information (draft labeling text).

Appendix B contains the results from the verbal and written prescription studies.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[d] identified 107 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%**.** These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search and the FDA Prescription Simulation Study. 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%	6
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	113
Low similarity name pair: combined match percentage score ≤54%	16

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

Our analysis of the 135 names contained in Table 1 determined 135 names will not 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 Medical Imaging Products (DMIP) via e-mail on May 23, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMIP on May 25, 2017, they stated no additional concerns with the proposed proprietary name, Gleolan.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have further questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO THE APPLICANT

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

[d] POCA search conducted on (4/3/2017) in version 4.0.

If any of the proposed product characteristics as stated in your March 27, 2017 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.

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. [e]

[e] 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[f]. 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.,

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

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.

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. Gleolan Study (Conducted on 4/10/2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Gleolan 30mg/ml 50ml po once 3 hrs prior to surgery Outpatient Prescription: Gleolan Bring to clinic #1 vial	Gleolan Bring to Clinic #1 vial

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

299 People Received Study
79 People Responded

Total	23	33	23	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BLIOLAN	0	1	0	1
GEODON	0	0	1	1
GILOLAND	0	1	0	1
GIOLAN	0	1	0	1
GLADAN	0	0	1	1
GLEALAN	0	0	1	1

GLEDAN	0	0	1	1
GLEEOLAND	0	1	0	1
GLEODAN	0	0	1	1
GLEOLAM	0	1	1	2
GLEOLAN	18	4	6	28
GLEOLAR	1	0	0	1
GLEOLEA	0	1	0	1
GLEOLIAM	0	1	0	1
GLEOLIAN	0	1	0	1
GLEOLIENT	0	1	0	1
GLESLAN	1	0	0	1
GLIOGLAND	0	1	0	1
GLIOLAM	0	1	0	1
GLIOLAN	1	11	0	12
GLIOLAND	0	2	0	2
GLIOLEN	0	1	0	1
GLIOLIAN	0	2	0	2
GLOALAM	0	0	1	1
GLOALAN	0	0	1	1
GLODAM	0	0	1	1
GLODAN	0	0	2	2
GLODON	0	0	1	1
GLOLAN	1	0	0	1
GLOOLAN	1	0	5	6
LEOLAN	0	1	0	1
LEOLIAN	0	1	0	1

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

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.	Gleolan	100	Subject of this review.
2.	Gliolan***	92	Proposed proprietary name for NDA 208630 found unacceptable by DMEPA (OSE#2016-11908377). NDA 208630 currently being reviewed under new proprietary name Gleolan (subject of this review).
3.	Glauline	70	The letter 'i' vs. 'a' in the sixth position and the additional letter 'e' at the end of Glauline provides some orthographic differences. Gleolan has one additional syllable. The second syllables (-line vs. –o-) of this name pair sound different. Dose: 1 drop vs. 20 mg/kg Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Access to the drug will be limited to neurosurgeons that have completed a risk management training program. Therefore, in this scenario, due to the above mentioned factors and the phonetic differences, we find this name pair acceptable.

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.**
4.	Levulan	70	The first letter of the name pair G- vs. L- is orthographically dissimilar. Gleolan contains an upstroke letter –l- in the second position which is absent from Levulan. The first syllables of this name pair (Gle- vs. Lev-) and second syllables (“o” vs. “u”) sound different. Strength: 1.5 g vs. 0.05 mg/ mL, 0.5 mg/ mL, 1 mg/mL, 2 mg/mL Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Access to the drug will be limited to neurosurgeons that have completed a risk management training program. Therefore, in this scenario, due to the above mentioned factors and the orthographic and phonetic differences, we find this name pair acceptable.

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.**
5.	Flolan	72	The first letter of the name pair G- vs. F- and the letter –e- in the third position of Gleolan which is absent in Flolan provides some orthographic differences. The first syllables of this name pair (Gle- vs. Flo-) sound different. Furthermore, the name Gleolan contains an added syllable. Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Access to the drug will be limited to neurosurgeons that have completed a risk management training program. Therefore, in this scenario, due to the above mentioned factors and the orthographic and phonetic differences, we find this name pair acceptable.

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.	Exolan	70	Gleolan contains an upstroke letter –l- in the second position which is absent from Exolan. The first syllables of this name pair (Gle- vs. Ex-) sound different. Product differences in strength, dose, frequency, route of administration and end users are sufficient. Strength: 1.5 gm vs. 25 mg, 50 mg, 100 mg Dose: 20 mg/kg before anesthesia vs. up to 100 mg three times daily. Frequency of administration: once vs three times a day Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Access to the drug will be limited to neurosurgeons that have completed a risk management training program. Therefore, in this scenario, due to the above mentioned factors and the orthographic and phonetic differences, we find this name pair acceptable.

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 (%)
7.	Clodan	65
8.	Lanolin	66
9.	Claforan	62
10.	Glycerin	59

No.	Name	POCA Score (%)
11.	Cleocin T	58
12.	Cleocin-T	58
13.	(b) (4)***	61
14.	Levlen	60
15.	Exelon	58
16.	Calan	56
17.	Gleostine	61
18.	Glycolax	60
19.	Gleevec	55
20.	Lavoclen	60
21.	Zaleplon	60
22.	Melphalan	56
23.	Gel-One	64
24.	Delone	56
25.	Glucagen	58
26.	Dologen	57
27.	Glaucol	56
28.	Goserelin	56
29.	Gablofen	59
30.	Glucagon	58
31.	Gel-Kam	56
32.	Cala-Gen	56
33.	Glo-Sel	58
34.	Haelan	58
35.	Gel-Tin	56
36.	Glucovance	56

No.	Name	POCA Score (%)
37.	Tronolane	56
38.	Logen	58
39.	Geocillin	56
40.	Geone	52
41.	Gentlelax	50
42.	Genozol	47
43.	Eugenol	46
44.	Naloxegol	44

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: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	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**
45.	Geodon	56	Phonetically, the first syllables ("Gle" vs. "Ge") and third syllables ("lan" vs "don") of this name pair provide sufficient phonetic differences. With regard to product characteristics, Gleolan and Geodon differ in terms of strength (*1.5gm vs. 20 mg, 40 mg, 60 mg, 80 mg*), frequency of administration (*once vs. twice daily or as needed [for intramuscular route of administration]*), and dosage form (*capsules and powder for solution for injection vs. powder for oral solution*). Dosing of Gleolan is weight-based (*20 mg/kg*) and dosing overlap with Geodon (*oral: 20mg to 80 mg; intramuscular: 10-40 mg per day*) appears unlikely when the Gleolan dose is expressed in 'mg'. Additionally, Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Gleolan will only be used by neurosurgeons who have completed a manufacturer mandated training program on the use of fluorescence in surgery. Prescribers of Gleolan must be certified neurosurgeons; in the absence of this certification, the neurosurgeon will not be able to secure Gleolan from the hospital pharmacy for his/her surgical use. Therefore, in this scenario, due to the above mentioned factors and the phonetic differences, we find this name pair acceptable.
46.	Cleocin	68	This name pair has sufficient orthographic and phonetic differences.
47.	Dalalone	61	This name pair has sufficient orthographic and phonetic differences.
48.	Glycron	62	This name pair has sufficient orthographic and phonetic differences.
49.	Oxilan	62	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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**
50.	Oxilan-300	62	This name pair has sufficient orthographic and phonetic differences.
51.	Oxilan-350	62	This name pair has sufficient orthographic and phonetic differences.
52.	Clolar	60	This name pair has sufficient phonetic differences. Dose: 20 mg/kg vs. 52 mg/m^2 Additionally, Gleolan is used for the real time detection and visualization of malignant tissue during glioma surgery using operating microscopes equipped with a blue light emitting light source. Gleolan will only be used by neurosurgeons who have completed a manufacturer mandated training program on the use of fluorescence in surgery. Prescribers of Gleolan must be certified neurosurgeons; in the absence of this certification, the neurosurgeon will not be able to secure Gleolan from the hospital pharmacy for his/her surgical use. Therefore, in this scenario, due to the above mentioned factors and the phonetic differences, we find this name pair acceptable.
53.	Glycine	56	This name pair has sufficient orthographic and phonetic differences.
54.	Verelan	60	This name pair has sufficient orthographic and phonetic differences.
55.	Glytone	59	This name pair has sufficient orthographic and phonetic differences.
56.	Gliadel	58	This name pair has sufficient orthographic and phonetic differences.
57.	Galzin	55	This name pair has sufficient orthographic and phonetic differences.
58.	Acclean	58	This name pair has sufficient orthographic and phonetic differences.
59.	Probalan	56	This name pair has sufficient orthographic and phonetic differences.

No.	**Proposed name: Gleolan** **Established name: 5-Aminolevulinic Acid HCl** **Dosage form: Powder for oral solution** **Strength(s): 1.5 grams per vial** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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**
60.	Glutol	56	This name pair has sufficient orthographic and phonetic differences.
61.	Collagen	60	This name pair has sufficient orthographic and phonetic differences.
62.	Euglucon	55	This name pair has sufficient orthographic and phonetic differences.
63.	Qoliana	55	This name pair has sufficient orthographic and phonetic differences.
64.	Reglan	59	This name pair has sufficient orthographic and phonetic differences.
65.	Blenoxane	56	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 (%)
66.	Geone	52
67.	Gentlelax	50
68.	Halenol	50
69.	Genozol	47
70.	Altenol	46
71.	Eugenol	46
72.	Gynogen La 20	46
73.	Naloxegol	44
74.	Gentasol	41

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
75.	Pullulan	61	This is not a drug. It is an allergenic extract.
76.	Drolban	62	Brand discontinued with no generic equivalent available. NDA 012936 withdrawn FR effective 03/02/1994.
77.	Glaucon	66	Product deactivated per Redbook; no generics available.
78.	Gammolin	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
79.	Eqvalan	62	Veterinary Product.
80.	Glaucine	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
81.	Glycolide	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
82.	Bee Pollen	60	This is not a drug. It is an allergen.
83.	Glycogen	62	This is an internationally marketed product in the UK, Israel, Ukaraine, France, Poland, Sweden and Singapore
84.	Glycolate	62	This is not a drug. It is an ester/salt of glycolic acid.
85.	Peg-60 lanolin	64	This is not a drug. Lanolin is used in industrial hand cleaners, soaps, suntan preparations, creams, emollients, ointment bases, and hoof dressings.
86.	Peg-75 lanolin	64	This is not a drug. Lanolin is used in industrial hand cleaners, soaps, suntan preparations, creams, emollients, ointment bases, and hoof dressings.
87.	Surolan	57	Veterinary product
88.	Glucoscan	58	Brand discontinued with no generic equivalent available. NDA017907 withdrawn FR effective 12/7/2007.

No.	Name	POCA Score (%)	Failure preventions
89.	Cholan	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
90.	Cleanzing!	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases
91.	DalganG	56	Brand discontinued with no generic equivalent available. NDA 019082 withdrawn FR effective 09/30/2000.
92.	Fluogen	55	International product formerly marketed in Brazil.
93.	Gallamine	60	Brand discontinued with no generic equivalent available. NDA 007842 withdrawn FR effective 9/22/1999.
94.	Glyoxal	55	This is not a drug. It is a homeopathic agent
95.	Lorfan	55	Brand discontinued with no generic equivalent available. NDA 010423 withdrawn FR effective 09/17/2001.
96.	Vallergan	55	International product marketed in Ireland, Australia, New Zealand, Norway and South Africa
97.	Gelatin	58	This is not a drug. It is a food and cosmetic additive.
98.	Lergoban	58	Brand discontinued with no generic equivalent available. NDA 011945 withdrawn FR effective 03/02/1994.
99.	Otoalgan	54	Brand discontinued with no generic equivalent available.
100.	Melanol	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
101.	Gen-lanta	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
102.	Aerolone	50	Brand discontinued with no generic equivalent available. NDA 007245 withdrawn FR effective 03/02/1994.

No.	Name	POCA Score (%)	Failure preventions
103.	Oleanolate	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
104.	Gen Lax	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
105.	Solganal	48	Discontinued drug product in US market, no generics available. International product marketed in Germany, Netherlands, Australia, Canada.
106.	Longrange	48	Veterinary Product
107.	Geraniol	46	This is not a drug. It is an allergen.
108.	Aogel	40	This is not a drug. It is a hand sanitizer.

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

No.	Name	POCA Score (%)
109.	Kaolin	60
110.	Klaron	60
111.	Levolet	59
112.	Myleran	58
113.	Nelova 1/50 M	58
114.	Pileran	58
115.	Deltalin	58
116.	Agrylin	58
117.	Biolon	57
118.	Lidodan	56
119.	Bellalphen	56
120.	Kliovance	56
121.	Brolene	56
122.	Prelone	56
123.	Calel-D	56
124.	Trilone	56
125.	Clinalog	56
126.	Demulen	56
127.	Demulen 1/35	56

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

No.	Name	POCA Score (%)
128.	Demulen 1/35-21	56
129.	Demulen 1/35-28	56
130.	Demulen 1/50	56
131.	Demulen 1/50-21	56
132.	Demulen 1/50-28	56
133.	Briellyn	56
134.	Decholin	55
135.	Clarine	55

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

/s/

IDALIA E RYCHLIK
05/25/2017

HINA S MEHTA
05/26/2017

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:	March 9, 2017
Application Type and Number:	NDA 208630
Product Name and Strength:	Gliolan (5-Aminolevulinic Acid Hydrochloride) powder for oral solution 1.5 gram vial
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	NX Development Corp.
Panorama #:	2016-11908377
DMEPA Primary Reviewer:	Idalia E. Rychlik, PharmD.
DMEPA Team Leader:	Hina Mehta, PharmD.
Associate Director (Acting):	Mishale Mistry, PharmD.
Division Director:	Todd Bridges, PharmD.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Gliolan, 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 December 14, 2016 proprietary name submission.

- Intended Pronunciation: Glee-ō-lăn
- Active Ingredient: 5-Aminolevulinic Acid Hydrochloride (5-ALA HCL)
- Indication of Use: imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery.
- Route of Administration: Oral
- Dosage Form: Powder for Reconstitution
- Strength: 1.5 gram vial (reconstituted concentration: 30 mg 5-ALA HCL per mL)
- Dose and Frequency: 20 mg/ kg 2-4 hours before anesthesia
- How Supplied: 50-ml clear, glass vial
- Storage: 25 °C (77 °F); excursions permitted to 15-30 °C (59-86 °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 Medical Imaging Products (DMIP) 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

The proposed proprietary name, Gliolan, contains the United States Adopted Name (USAN) stems *–io-* and *Gli-*.[a] The 'io' stem, either as a prefix or infix, is used by the USAN Council to indicate an iodine containing contrast media (e.g., *io*damide, adip*io*done). The 'gli' stem, as prefix, is used by the USAN Council to indicate anti-hyperglycemic drug products. Since Gliolan

[a] USAN stem search conducted on 12/23/2016.

is not an iodine containing contrast media agent, nor an anti-hyperglycemic drug, the incorporation of this stem in the proposed proprietary name is inconsistent with the intended USAN meaning. Proprietary names should not incorporate United States Adopted Name (USAN) stems in the position that USAN designates for the stem.[b] The use of a USAN stem within the proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names.

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Gliolan, is derived from the root "glio," which is intended to represent glioblastoma. This proprietary name is comprised of a single word containing two USAN stems (see section 2.2.1 and 3.1) that are misleading and may contribute to medication error.

2.2.3 FDA Name Simulation Studies

Ninety-five (95) practitioners participated in DMEPA's prescription studies. One response was a close variation to a currently marketed product.

One participant misinterpreted the name Gliolan as "Cleolan" in the voice prescription, which is a close variation to the currently marketed product "Cleocin". Orthographically, we note that the suffixes of this name pair have sufficient orthographic differences due to absence of an upstroke (the letter "l" in Gliolan vs. Cleocin). Phonetically, the third syllable of this name pair has sufficient phonetic differences ("-lan" vs. "-cin"). In addition, both "Gliolan" and "Cleocin" differ in strength (1.5 gm vs. varies based on formulation) and dose (20 mg/kg before anesthesia vs. 150 mg to 2,700 mg per day depending on formulation). As Cleocin is available in various strengths, dose and strength would need to be specified. "Gliolan" and "Cleocin" also differ in frequency of administration (once vs. twice, three times, or four times a day). "Cleocin" is available as capsules, cream, lotion, gel, granules, and vaginal suppositories) whereas Gliolan is available as a powder for reconstitution. We evaluate this name pair in Appendix E.

Seventy-nine (79) participants interpreted the name correctly. 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, December 22, 2016 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

[b] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM39899

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names retrieved from our POCA search[c] and also includes names identified from the FDA Prescription Simulation Study. These names 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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	106
Low similarity name pair: combined match percentage score ≤54%	27

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

Our analysis of the 136 names contained in Table 1 determined that none of the names will 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 Division of Medical Imaging Products (DMIP) via e-mail on March 2, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMIP on March 8, 2017, they stated no additional concerns with the proposed proprietary name, Gliolan.

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name contains two USAN stems, –io- and Gli-. Therefore, the decision to deny the name will be communicated to the Applicant/Sponsor via letter (See ***(Section 3.1).***

If you have further questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Gliolan, and have concluded that this name is unacceptable for the following reasons:

The proposed proprietary name, Gliolan, contains the United States Adopted Name (USAN) stems *–io-* and *Gli-*.[d] The 'io' stem, either as a prefix or infix, is used by the USAN Council to indicate an iodine containing contrast media (e.g., *io*damide, adip*io*done). The 'gli' stem, as

[c] POCA search conducted on (1/10/2017) in version 4.0.

[d] USAN stem search conducted on 12/23/2016.

prefix, is used by the USAN Council to indicate anti-hyperglycemic drug products. Since Gliolan is not an iodine containing contrast media agent, nor an anti-hyperglycemic drug, the incorporation of these stems in the proposed proprietary name is inconsistent with the intended USAN meanings. Proprietary names should not incorporate United States Adopted Name (USAN) stems in the position that USAN designates for the stem.[e] The use of a USAN stem within the proprietary names, even when used consistently with the USAN meaning, can result in multiple similar proprietary names and proprietary names that are similar to established names, thus increasing the chance of confusion among those drugs, which may compromise patient safety. To reduce the potential for confusion, USAN stems should not be incorporated into proprietary names.

.

[e] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM39899

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. [f]

[f] 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[g]. 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.,

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

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.

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	**Y/N**	Do the syllables have different phonologic processes, such vowel reduction, assimilation,

	upstroke/downstroke letters present in the names?		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

<table>
<tr><td></td><td colspan="2">which may potentiate confusion between a name pair with moderate similarity.

• Similar sounding doses: 15 mg is similar in sound to 50 mg</td></tr>
<tr><td rowspan="2">Step 2</td><td colspan="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 <u>with</u> overlapping or similar strengths or doses.</td></tr>
<tr><td>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?</td><td>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?</td></tr>
</table>

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. Gliolan Study (Conducted on 1/3/2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Gliolan 30 mg/mL administer 3 hours prior to surgery 45mL Outpatient Prescription: Gliolan Bring to clinic Disp. 1 vial	Gliolan Bring to Clinic #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

305 People Received Study
95 People Responded

Study Name: Gliolan

Total	33	27	35	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
CLEOLAN	0	1	0	1
GEWOLAND	0	1	0	1
GLEEOLAN	0	1	0	1
GLEOLAM	0	1	0	1
GLEOLAN	0	5	0	5
GLEOLAND	0	2	0	2
GLIOBAN	1	0	0	1
GLIOLAM	0	1	0	1
GLIOLAN	31	14	34	79
GUIOLAN	0	1	0	1
MEIOLAN	0	0	1	1
SLIOLAN	1	0	0	1

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

No	**Proposed name: Gliolan** **Established name: 5-Aminolevulinic Acid Hydrochloride** **Dosage form: Powder for Reconstitution** **Strength(s): 1.5 gm vial (30 mg/ mL)** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	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.	Gliolan	100	Subject of review
2.	Flolan	72	The first letter of the name pair G- vs. F- is orthographically dissimilar. Gliolan contains an upstroke dotted letter –i- in the third position which is absent from Flolan; this provides some orthographic differences The first syllables of this name pair (Gli- vs. Flo-) sound different. Furthermore, the name Gliolan contains an added syllable. Although Gliolan and Flolan have overlapping strength (1.5 mg vials) the products differ in dosing and route of administration.. Dose: Flolan initiated at 2 ng/kg/minute, titrate 1- to 2-ng/kg/min by 15 minute increments at intervals sufficient to produce clinical response and is dosed as a rate of mL/hour vs. Gliolan 20 mg/ kg 2-4 hours before anesthesia Route of administration: Flolan is administered as a continuous intravenous infusion vs. Gliolan is taken orally as a one-time dose.

No	**Proposed name: Gliolan** **Established name: 5-Aminolevulinic Acid Hydrochloride** **Dosage form: Powder for Reconstitution** **Strength(s): 1.5 gm vial (30 mg/ mL)** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.**
3.	Glauline	70	Glauline contains an extra letter –e at the end which is absent from Gliolan. Gliolan contains an upstroke dotted letter –i- in the third position which is absent from Glauline. The second (-u- vs. –o-) and third syllables (-line vs. –lan) of this name pair sound different. Gliolan has an additional syllable. Products differences in dosing, route of administration and end users are sufficient. Dose: Glauline 1 drop in affected eye twice daily vs. Gliolan 20 mg/ kg 2-4 hours before anesthesia Route of administration: Glauline is an ophthalmic eye drop vs. Gliolan is taken orally as a one-time dose.

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

No.	Name	POCA Score (%)
1.	Biolon	66
2.	Calan	55
3.	Exolan	62
4.	Gablofen	56
5.	(b) (4) ***	60
6.	Gel-One	57
7.	Gel-Tin	55
8.	(b) (4) ***	58
9.	Glofil-125	56
10.	Glucagen	56

No.	Name	POCA Score (%)
11.	Glucagon	58
12.	Glycerin	59
13.	Glycolax	61
14.	Glyquin	60
15.	Glytrin	62
16.	Goniosol	48
17.	Granisol	50
18.	Isolan	64
19.	Lanolin	68
20.	Levulan	62
21.	Miglitol	55
22.	Mitrolan	58
23.	Mobilan	58
24.	Pilagan	56
25.	Silanol	53
26.	Uni-lan	58

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: Gliolan** **Established name: 5-Aminolevulinic Acid Hydrochloride** **Dosage form: Powder for Reconstitution** **Strength(s): 1.5 gm vial (30 mg/ mL)** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.	Cleocin	64 (Phone=73)	The suffixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke, the letter "l" in the suffix, which is absent from Cleocin. The third syllables ('lan' vs. 'cin') of this name pair sound different. In addition, both Gliolan and Cleocin differ substantially in their product characteristics. Strength: Gliolan 1.5 gm vs. Cleocin varies based on formulation Dose: Gliolan 20 mg/kg before anesthesia vs. Cleocin 150 mg to 2,700 mg per day depending on formulation Cleocin is available in various strengths, therefore the dose and strength would need to be specified. Frequency of administration: Gliolan is given only once vs. Cleocin twice, three times, or four times a day Dosage form: Gliolan is available as a powder for reconstitution vs. Cleocin is available as capsules, cream, lotion, gel, granules, and vaginal suppositories
2.	Clolar	60	The prefixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different. The name Gliolan contains an extra syllable.

No	**Proposed name: Gliolan** **Established name: 5-Aminolevulinic Acid Hydrochloride** **Dosage form: Powder for Reconstitution** **Strength(s): 1.5 gm vial (30 mg/ mL)** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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**
3.	Galzin	62	The prefixes/suffixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different. The name Gliolan contains an extra syllable.
4.	Glaucol	56	The prefixes/suffixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke, the letter "l" in the suffix, which is absent from Glaucol. The first/second/third syllables of this name pair sound different.
5.	Gleostine	55	The suffixes of this name pair have sufficient orthographic differences. Gleostine has an additional 2 letters "n" and "e" at the end of the name and Gliolan has an upstroke the letter "l" in the suffix, where there is an "s" in Gleostine. The third syllables of this name pair sound sufficiently different.

No	**Proposed name: Gliolan** **Established name: 5-Aminolevulinic Acid Hydrochloride** **Dosage form: Powder for Reconstitution** **Strength(s): 1.5 gm vial (30 mg/ mL)** **Usual Dose: 20 mg/ kg 2-4 hours prior to surgery**	**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.	Gliadel	60	The suffixes of this name pair have sufficient orthographic differences. Gliadel has an upstroke in the last position which is absent from Gliolan. The second/third syllables of this name pair sound different. In addition, both Gliolan and Gliadel differ in their product characteristics. Strength: Gliolan 1.5 gm vs. Gliadel 7.7 mg wafer and 100 mg powder vial for injection Dose: Gliolan 20 mg/kg before anesthesia vs. Gliadel 8 wafers implanted after resection or various dosing parameters for IV, therefore the dose and dosage form would need to be specified. Frequency of administration: Gliolan is given only once vs. Gliadel is surgically implanted or given via IV infusion. Dosage form: Gliolan is available as a powder for reconstitution vs. Gliadel is available as an implant or under generic IV powder for reconstitution.
7.	Glutol	56	The suffixes of this name pair has sufficient orthographic differences. The first/second syllables of this name pair sound different. Gliolan also contains an additional syllable.
8.	Glycine	60	The prefixes/ suffixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in its suffix, which is absent from Glycine. Glycine has a downstroke in its prefix which is absent from Gliolan. The first/second syllables of this name pair sound different. Gliolan also contains an additional syllable.

No	**Proposed name:** Gliolan **Established name:** 5-Aminolevulinic Acid Hydrochloride **Dosage form:** Powder for Reconstitution **Strength(s):** 1.5 gm vial (30 mg/ mL) **Usual Dose:** 20 mg/ kg 2-4 hours prior to surgery	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**
9.	Glycron	62	The prefixes/suffixes of this name pair have sufficient orthographic differences. Glycron has a down stroke, the letter "y" in the prefix which is absent from Gliolan. Gliolan contains an upstroke in its suffix which is absent from Glycron. The first/second syllables of this name pair sound different. Gliolan also contains an additional syllable.
10.	Glytone	59	The prefixes/ suffixes of this name pair have sufficient orthographic differences. Gliolan contains an upstroke in its suffix which is absent from Glytone. The first/second syllables of this name pair sound different. Gliolan also contains an extra syllable.
11.	Ioxilan	63	The prefixes/infixes of this name pair have sufficient orthographic differences. The first/second syllables of this name pair sound different.
12.	Lidodan	64	The prefixes, "gli" verse "li" and infixes, "o" verses "do" of this name pair have sufficient orthographic differences. The first/third syllables of this name pair sound different.
13.	Oxilan	66	The prefixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in the second position which is absent from Oxilan. The first syllable of this name pair sound different.
14.	Oxilan-300	66	The prefixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in the second position which is absent from Oxilan. The first syllables of this name pair sound different, and Oxilan-300 contains a numerical modifier.

No	**Proposed name:** Gliolan **Established name:** 5-Aminolevulinic Acid Hydrochloride **Dosage form:** Powder for Reconstitution **Strength(s):** 1.5 gm vial (30 mg/ mL) **Usual Dose:** 20 mg/ kg 2-4 hours prior to surgery	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.	Oxilan-350	66	The prefixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in the second position which is absent from Oxilan. The first syllables of this name pair sound different, and Oxilan-350 contains a numerical modifier.
16.	Qoliana	58	The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in the second position which is absent from Qoliana. The first/second/third syllables of this name pair sound different.
17.	Quinalan	60	The prefixes/infixes of this name pair have sufficient orthographic differences. Gliolan has an upstroke in the second position which is absent from Quinalan. The first/second syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	Agoral Plain	50
2.	Align	48
3.	Angidol	48
4.	Angilol	52
5.	Angiopine 40 La	42
6.	Bal In Oil	52
7.	Elliona	49
8.	Elliona 1/35	49
9.	Elliona 7/7/7	49
10.	Galangal Oil	52
11.	Geraniol	46
12.	Gold Cation (3+)	48

No.	Name	POCA Score (%)
13.	Ilopan	54
14.	Iodo Plain	50
15.	lanolin Oil	52
16.	Licon	52
17.	Lignospan	54
18.	Linalool, ()-	54
19.	Linalool, (-)-	54
20.	Linalool, (+)-	54
21.	Linalool, (+-)-	54
22.	Logilia	50
23.	Otoalgan	53
24.	Solganal	48

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.	Cholan	58	Discontinued product (Cholan-HMB), no generic available (per Redbook).
2.	Gallamine	58	Brand discontinued with no generic equivalent available. NDA 007842 withdrawn FR effective 9/22/1999.
3.	Galliprant	56	Veterinary Product
4.	Gammolin	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
5.	Gitalin	60	International product marketed in Indonesia
6.	Glaucine	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Glaucon	65	Product deactivated per Redbook; no generics available.
8.	Gliotoxin	58	This is not a drug. It is a sulfur-containing mycotoxin. Mycotoxin products may be used in homeopathic medicine.
9.	Glucoscan	60	Brand discontinued with no generic equivalent available. NDA017907 withdrawn FR effective 12/7/2007.

No.	Name	POCA Score (%)	Failure preventions
10.	Glycogen	58	This is an internationally marketed product in the UK, Israel, Ukaraine, France, Poland, Sweden and Singapore
11.	Glycolate	60	This is not a drug. It is an ester/salt of glycolic acid.
12.	Glycolide	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Glyoxal	56	This is not a drug. It is a homeopathic agent
14.	(b) (4) ***	56	Proposed proprietary name for IND (b) (4) found unacceptable by OPDP (OSE# (b) (4)). IND (b) (4) approved under new proprietary name (b) (4).
15.	Guaietolin	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
16.	Iotrolan	60	Brand discontinued with no generic equivalent available. NDA 019580 withdrawn FR effective 6/10/1999.
17.	Kliovance	60	International product marketed in New Zealand, Australia and the UK.
18.	lanozin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Midazolan	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Peg-60 Lanolin	64	This is not a drug. Lanolin is used in industrial hand cleaners, soaps, suntan preparations, creams, emollients, ointment bases, and hoof dressings.
21.	Peg-75 Lanolin	64	This is not a drug. Lanolin is used in industrial hand cleaners, soaps, suntan preparations, creams, emollients, ointment bases, and hoof dressings.
22.	Pullulan	61	This is not a drug. It is an allergenic extract.
23.	Solian	57	International product marketed in the UK, Belgium, China, Australia, Austria, Czech Rep, Denmark and France
24.	Surolan	57	Veterinary product
25.	Triolein	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
26.	Vivalan	58	Formerly Marketed International Product per Toxicology & Drug Products search. No generics available.

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

No.	Name	POCA Score (%)
1.	Agri-Cillin	58
2.	Agrylin	65
3.	Aliclen	56
4.	(b) (4)***	55
5.	Azlocillin	56
6.	Briellyn***	57
7.	Ciclodan	55
8.	Claforan	62
9.	Clairvan	59
10.	Clinalog	63
11.	Clinsol	55
12.	Clodan	65
13.	Colicon	55
14.	Collagen	56
15.	Dalalone	58
16.	Dicloran	57
17.	Diovan	60
18.	Drolban	62
19.	Folbalin	55
20.	(b) (4)***	56
21.	Kaolin	64
22.	Klaron	58
23.	Lavoclen	56
24.	Lialda	56
25.	Lif-O-Gen	56
26.	Lipofen	55
27.	Lorfan	55

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

No.	Name	POCA Score (%)
28.	Mizollen	57
29.	Mol-Iron	57
30.	Myolin	56
31.	Novolin	57
32.	Novolin 70/30	57
33.	Novolin N	56
34.	Panglobulin	56
35.	Pileran	58
36.	Tilarin	57
37.	Trilone	56
38.	Trinalin	56
39.	Triotann	56
40.	Xylitan	55

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

/s/

HINA S MEHTA on behalf of IDALIA E RYCHLIK
03/09/2017

HINA S MEHTA
03/09/2017

MISHALE P MISTRY
03/09/2017

TODD D BRIDGES
03/09/2017