CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

210997Orig1s000
210997Orig2s000

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**

Date of This Review:	December 13, 2017
Application Type and Number:	NDA 210997
Product Name and Strength:	Glyrx-PF (glycopyrrolate injection, USP), 0.2 mg/mL
Total Product Strength:	0.2 mg/1 mL and 0.4 mg/2 mL
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Exela Pharma Sciences
Panorama #:	2017- 17716055 2017- 17717300
DMEPA Safety Evaluator:	Millie Shah, PharmD, BCPS
DMEPA Team Leader:	Otto L. Townsend, PharmD
DMEPA Deputy Director:	Irene Chan, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Glyrx-PF, 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 September 22, 2017 proprietary name submission.

- Intended Pronunciation: gli ~ rex
- Active Ingredient: Glycopyrrolate
- Indication of Use: Preanesthetic medication, intraoperative medication, reversal of neuromuscular blockade, peptic ulcer
- Route of Administration: intravenous or intramuscular
- Dosage Form: injection
- Strength: 0.2 mg/1 mL and 0.4 mg/2 mL
- Dose and Frequency:

  Adults:

  - Preanesthetic Medication: administered 0.004 mg/kg by intramuscular injection, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia.
  - Intraoperative Medication: administered intravenously as single doses of 0.1 mg and repeated, as needed, at intervals of 2 to 3 minutes.
  - Reversal of Neuromuscular Blockade: administered 0.2 mg for each 1mg of neostigmine or 5 mg of pyridostigmine.
  - Peptic Ulcer: 0.1 mg administered at 4 hour intervals, 3 or 4 times daily intravenously or intramuscularly.

  Pediatric patients:

  - Infants (1 month to 2 years of age): may require up to 0.009 mg/kg.
- How Supplied: 0.2 mg/1 mL vial and 0.4 mg/2 mL vial
- Storage: 20° to 25°C (68° to 77°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. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, Glyrx-PF, is derived from GLY (the first three letters of the active ingredient "Glycopyrrolate"), adding "RX" to convey that it is a prescription drug and adding "PF" to indicate that it is a preservative free product. This proprietary name is comprised of the root name, "Glyrx", and the modifier "PF." The modifier is discussed further in Section 2.2.5.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE e-mail dated October 10, 2017, the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.4 FDA Name Simulation Studies

Seventy-two 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 Analysis of the Proposed Modifier "PF"

The proposed modifier 'PF' is intended to mean 'Preservative Free.' We confirmed with the Office of Pharmaceutical Quality (OPQ) that the product is preservative free. If approved, Glyrx-PF will be the first preservative free formulation of glycopyrrolate injection. The modifier 'PF' is used for other currently marketed products (e.g. Cosopt PF, Aminosyn-PF, Oasis Tears PF) to indicate that the product is preservative free. Additionally, to our knowledge, the modifier 'PF' has not been cited as a source of confusion in postmarketing reports.

In our evaluation, we also considered the risk of name confusion if the modifier is dropped. We note that omission and oversight of modifiers is cited in literature as a common cause of medication errors.[b] We note there is no currently marketed 'Glyrx' product in the marketplace that could be confused with Glyrx-PF if the modifier is dropped. Additionally, we considered

[a] USAN stem search conducted on September 27, 2017.

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

the name 'Glyrx' (without the modifier) in this review and determined that the risk of confusion is minimal. Thus, given the totality of factors considered above, we conclude that the modifier 'PF' is acceptable for the proposed product.

2.2.6 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 26 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.

2.2.7 Names with Strength Overlap and Potential Orthographic, Spelling, and Phonetic Similarities

The proposed product, Glyrx-PF will be available in 0.2 mg/1 mL and 0.4 mg/2 mL strengths. Since the 0.4 mg/2 mL strength is not a typical strength that is commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify names with strength overlap. Names identified in the eDRLS database not likely to be confused due to notable spelling, orthographic and phonetic differences are listed in Appendix I.

2.2.8 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%	3
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	23
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 26 names contained in Table 1 determined none of the names will not pose a risk for confusion as described in Appendices C through H.

2.2.10 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) via e-mail on December 8, 2017. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the

[c] POCA search conducted on October 4, 2017 in version 4.1.

DAAAP on December 13, 2017, they stated no additional concerns with the proposed proprietary name, Glyrx-PF.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Davis Mathew, OSE project manager, at 240-402-4559.

3.1 COMMENTS TO THE APPLICANT

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

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

[d] 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[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g.,

[e] 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

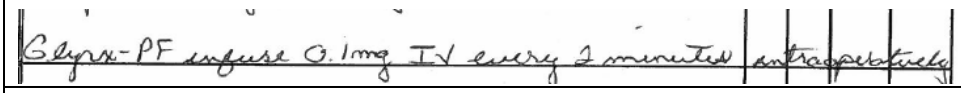
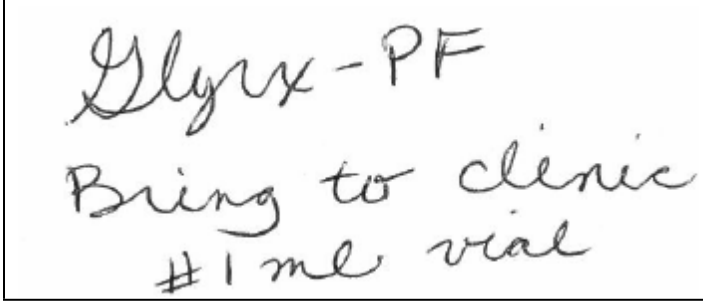
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.	
	Orthographic 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. Glyrx-PF Study (Conducted on October 17, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Glyrx-PF Bring to clinic Dispense 1 mL vial

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

293 People Received Study

72 People Responded

Study Name: Glyrx PF

Total	28	20	24	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
BLIREX PF	0	1	0	1
BLYREX PF	0	3	0	3
GLYCX	1	0	0	1
GLYIX PF	1	0	0	1
GLYREX PF	0	11	0	11
GLYREX TF	0	1	0	1
GLYREX TS	0	1	0	1
GLYREX-TF	0	1	0	1
GLYRX	3	0	0	3
GLYRX - PF	1	0	0	1
GLYRX PF	1	1	1	3
GLYRX- PF	0	0	2	2
GLYRX-PF	19	0	21	40
GLYVX-PF	1	0	0	1

GLYX-PF	1	0	0	1
GYREX PF	0	1	0	1

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

No.	**Proposed name:** Glyrx-PF **Established name:** glycopyrrolate **Dosage form:** injection **Strength(s):** 0.2 mg/mL **Usual Dose:** Adults: • Preanesthetic Medication: administered 0.004 mg/kg by intramuscular injection, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia. • Intraoperative Medication: administered intravenously as single doses of 0.1 mg and repeated, as needed, at intervals of 2 to 3 minutes. • Reversal of Neuromuscular Blockade: administered 0.2 mg for each 1mg of neostigmine or 5 mg of pyridostigmine. • Peptic Ulcer: 0.1 mg administered at 4 hour intervals, 3 or 4 times daily intravenously or intramuscularly. Pediatric patients: • Infants (1 month to 2 years of age): may require up to 0.009 mg/kg.	**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.**
		POCA Search "Glyrx"	**POCA Search "Glyrxpf"**	
1.	Glyrx	100	76	Root name for subject of this review. "Glyrx" without a modifier is not available.
2.	Glyrx-PF	76	100	Subject of this review.
3.	Poly-Rx	71	60	Brand discontinued with no generic equivalent available. ANDA 061578 withdrawn FR effective 07/21/2017.

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 (%)	
		POCA Search "Glyrx"	**POCA Search "Glyrxpf"**
4.	Glyset	58	
5.	Glycron	55	

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

No.	**Proposed name:** Glyrx-PF **Established name:** glycopyrrolate **Dosage form:** injection **Strength(s):** 0.2 mg/mL **Usual Dose:** Adults: • Preanesthetic Medication: administered 0.004 mg/kg by intramuscular injection, given 30 to 60 minutes prior to the anticipated time of induction of anesthesia. • Intraoperative Medication: administered intravenously as single doses of 0.1 mg and repeated, as needed, at intervals of 2 to 3 minutes. • Reversal of Neuromuscular Blockade: administered 0.2 mg for each 1mg of neostigmine or 5 mg of pyridostigmine. • Peptic Ulcer: 0.1 mg administered at 4 hour intervals, 3 or 4 times daily intravenously or intramuscularly. Pediatric patients: Infants (1 month to 2 years of age): may require up to 0.009 mg/kg.	**POCA Score (%)**		**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
		POCA Search "Glyrx"	**POCA Search "Glyrxpf"**	
6.	Glytuss	62		This name pair has sufficient orthographic and phonetic differences.
7.	Gly-Cort	60		This name pair has sufficient orthographic and phonetic differences.
8.	Glycolax	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 (%)
9.	Not Applicable	

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

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Glyrx"	**POCA Search "Glyrxpf"**	
10.	Glycort	60		Brand discontinued with no generic equivalent available. ANDA 087489 withdrawn FR effective 02/02/2001.
11.	Glyoxal	58		Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)		Failure preventions
		POCA Search "Glyrx"	POCA Search "Glyrxpf"	
12.	Glycoprep		55	Brand discontinued with no generic equivalent available. ANDA 072319 withdrawn FR effective 02/02/2001.
13.	Glytrin	55		International product marketed in several foreign countries.

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

No.	Name	POCA Score (%)	
		POCA Search "Glyrx"	POCA Search "Glyrxpf"
14.	Selrx	63	
15.	Allerx PM		60
16.	Myorx	59	
17.	Colrex	58	
18.	Flarex	58	
19.	Syn-RX	58	
20.	Syrex	58	
21.	Xylarex	58	
22.	Flurox	57	
23.	Alrex	56	
24.	Dylix	56	
25.	Lymerix	56	
26.	Pyrlex PD		56
27.	Valrox	55	

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

No.	Name
1.	3CE SHIMMER PINK
2.	Aetna Callus Remover
3.	AHC Complex Choice EGF Booster
4.	antibacterial hand sanitizer

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

No.	Name
5.	Aqua Collagen Multi Vitamin Hydro Mask
6.	Aqua Collagen Solu tion Multi Vitamin Hydroge l Mask
7.	Atropine Sulfate
8.	Biellee Pollen Hydra Pure Brightening Cream
9.	BlanX White Shock White and Protect
10.	BRODA Acne
11.	CELL BOOSTING ESSENCE
12.	CHAGA Anti Wrinkle Eye with fermented chaga extract
13.	COPPER
14.	COTTONTAILS DIAPER RASH
15.	Diaper Rash
16.	Dr. Scholls
17.	Dr. Scholls Duragel Callus Removers
18.	EASYDEW DAILY DOUBLE HYDRA ESSENCE
19.	Emerald Green Neutral pH Anti-Bacterial Hand
20.	Evzio
21.	Fascy Moisture Bomb Hand Grapefruit 40mL
22.	Fascy Moisture Bomb Hand Milk 40mL
23.	Fascy Moisture Bomb Hand Peach 40mL
24.	Fascy Moisture Bomb Hand Strawberry 40mL
25.	Fascy Moisture Bomb Hand Violet 40mL
26.	Flomax
27.	GINSENG ROYAL SILK ESSENCE
28.	Glycopyrrolate
29.	GORDONS UREA 40
30.	Green
31.	HONEST TT MIST
32.	Hydromorphone HCl
33.	Ionite H
34.	LEADER DIAPER RASH
35.	LUGOLS SOLUTION
36.	Maximum Strength One Step Wart Remover Strips
37.	Maximum Strength Wart Remover Strips
38.	MSM (MoSaengMo)
39.	MYSTIC FOREST TOOTH
40.	Naloxone Hydrochloride
41.	NBF Gingival
42.	Nitroglycerin
43.	Nitroglycerin Transdermal Delivery System
44.	Nitroglycerin Transdermal System
45.	Nitrostat
46.	One-Step Wart Remover Clear

No.	Name
47.	Orbitol
48.	ORIPAN GOLD 80g
49.	PARAID One Step Wart Remover Strips
50.	Pedi-Quick One Step Callus Removers
51.	Personal Care Antibacterial Foaming Hand Wash
52.	PLACENTA EX ESSENCE
53.	Plak Smacker
54.	PREMIER VALUE DIAPER RASH
55.	Purple
56.	REBORNCELL AQUA RICH
57.	ReNK Essential Hydra Serum
58.	ReNK Time Lab Intense Age Renewal Serum
59.	Retin-A MICRO
60.	REVITAL PERFECTING DUAL AMPOULE
61.	Salicylic acid
62.	SELLA NATURAL BABY
63.	SELLA NATURAL BODY
64.	SELLA NATURAL HAIR
65.	SELLA PREMIUM NATURAL CLEANSING BAR
66.	SKINFOOD ROYAL HONEY ESSENTIAL EYE INDIVIDUAL SAMPLE
67.	SNAYTOX ESSENCE BOOSTER
68.	SPAI-SONS
69.	SUBSYS
70.	Tamsulosin hydrochloride
71.	Tayadent With Fluoride
72.	Tretinoin
73.	Tretinoin Gel Microsphere
74.	TROPICAL OCEAN TOOTH
75.	V Vitalizing Eye
76.	VerruStat Medicated Plantar Pads
77.	Wart Remover
78.	WESTERN FAMILY DIAPER RASH

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/s/

MILLIE C BRAHMBHATT
12/13/2017

OTTO L TOWNSEND
12/13/2017

IRENE Z CHAN
12/14/2017