CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208424Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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 28, 2016
Application Type and Number:	NDA 208424
Product Name and Strength:	GoNitro (Nitroglycerin) Sublingual Powder, 400 mcg per packet
Product Type:	Single ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	G. Pohl- Boskamp GmbH & Co. KG
Panorama #:	2016-8228507
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD
DMEPA Division Director:	Todd Bridges, RPh

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, GoNitro, which was previously found not acceptable under NDA 208424 on November 13, 2015, due to risk of name confusion with another in house proposed proprietary name (b) (4) *** for IND (b) (4).[1] We note that all product characteristics of GoNitro remain the same.

Since the application action date for NDA 208424 is June 10, 2016; and IND (b) (4) is active but without a NDA submission***, we are reevaluating the proposed proprietary name, GoNitro, for NDA 208424.

2 METHODS AND DISCUSSION

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 27, 2016, search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any additional names that represent a potential source of drug name confusion. Therefore, the proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your May 27, 2016, submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

[1] Stewart, J. Proprietary Name Review for GoNitro (NDA 208424). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2015 Nov 13. Panorama No. 2015-1272651.

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.

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

/s/

CHI-MING TU
05/28/2016

TODD D BRIDGES
05/29/2016

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 13, 2015
Application Type and Number:	NDA 208424
Product Name and Strength:	GoNitro (Nitroglycerin) Powder, 400 mcg per (b) (4)
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	G. Pohl-Boskamp GmbH & Co. KG
Panorama #:	2015-1272651
DMEPA Primary Reviewer:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD
DMEPA Deputy Director:	Lubna Merchant, M.S.; PharmD
DMEPA Division Director:	Todd Bridges, R.Ph.

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, GoNitro, 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 submitted an external name study, conducted by (b) (4) for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 18, 2015 proprietary name submission.

- Intended Pronunciation: GO-NYE-troh
- Active Ingredient: Nitroglycerin
- Indication of Use: Indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease
- Route of Administration: Sublingual
- Dosage Form: Powder for sublingual use
- Strength: 400 mcg (0.4 mg) per (b) (4)
- Dose and Frequency:
  • At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.
  • Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.
  • May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.
- How Supplied: Available in cartons of 12, 36 or 96 (b) (4)
- Storage: Store up to 25 °C (77 °F); excursions permitted between 5 – 40 °C (41 – 104 °F).
- Container and Closure Systems: unit-dose packs

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 Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's assessment of the proposed GoNitro.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant indicated in their submission that the proposed name, GoNitro, is derived from the concept of portability. The light, compact packets allow for the product to "go" with the patient conveniently in their pocket. The name also has connectivity to the active ingredient: nitroglycerin.

This proprietary name is comprised of a single word that contains reference to the active ingredient. However, many existing prescription nitroglycerin products are marketed with a proprietary name containing "Nitro", referencing nitroglycerin as well (e.g. Nitro-Dur, Nitrostat, Nitromist, etc.) Thus, we do not object to the inclusion of "Nitro" in the proposed name.

2.2.3 FDA Name Simulation Studies

Sixty-eight (68) 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. Fifty-six (56) practitioners correctly interpreted the proposed name as GoNitro. 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, October 28, 2015 e-mail, the Division of Cardiovascular & Renal Products (DCRP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 1 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search[2] organized as highly similar, moderately similar, or low similarity for further evaluation. Table 1 also includes names identified by (b) (4)

[1]USAN stem search conducted on September 1, 2015.

[2] POCA search conducted on September 30, 2015.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	132
Low similarity name pair: combined match percentage score ≤49%	74

2.2.6 Names with Potential Orthographic, Spelling, and Phonetic Similarities that overlap in strength

The proposed product, GoNitro will be available in strength of 400 mcg, which can be expressed as 0.4 mg. Since 0.4 mg is not a commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with GoNitro that were not identified in POCA, and found to have an overlap in strength with GoNitro. Three (3) names were identified from eDRLS for further analysis in Appendices C through H.

Table 1A. eDRLS Search Results	POCA score
GINSENG	38
GLYCOPYRROLATE	26
GORDONS UREA 40	42

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

Our analysis of the 208 names contained in Table 1 and the three (3) names in Table 1A determined 207 of the 208 of names will not pose a risk for confusion as described in Appendix C through H. However, the proposed name could be confused with (b) (4)***. The rationale for the risk of confusion is described below.

GoNitro vs. (b) (4)***

The proposed name, GoNitro, may be confused with the proposed name (b) (4)*** (b) (4) due to orthographic similarity as well as overlapping product characteristics that may increase the risk of wrong drug errors. (b) (4)*** is a pending name for IND (b) (4) within the Agency that is currently under review.

The orthographic similarity of GoNitro and (b) (4)*** stems from (b) (4)

(b) (4)

(b) (4)

Our conclusion differs from the external study submitted by the Sponsor. Since (b) (4)*** is a pending name within the Agency, it was not identified by (b) (4) in their external name study for GoNitro.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on November 6, 2015. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Cardiovascular and Renal Products (DCRP) on November 12, 2015, they stated no additional concerns with the proposed proprietary name, GoNitro.

[3] Institute for Safe Medication Practices. FDA Advise-ERR: Medication errors associated with levothyroxine products. ISMP Med Saf Alert Acute Care. 2000;5(18):3

3 CONCLUSIONS

The proposed proprietary name is not acceptable from a safety perspective. The proposed name is vulnerable to name confusion with (b) (4) ***. Therefore, the decision to deny the name will be communicated to the Applicant via letter (See ***3.1).***

If you have further questions or need clarifications, please contact Darrell Lyons, OSE project manager, at 301-796-4092.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, GoNitro, and conclude that this name could result in medication errors due to confusion with another product that is also under review. Therefore, the ultimate acceptability of your proposed proprietary name, GoNitro, is dependent upon which underlying application is approved first. If another product is approved prior to your product, with a name that would be confused with your proposed name of GoNitro, you will be requested to submit another name.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Table 4: Moderately Similar Name Pair Checklist (i.e., combined score is ≥50% to ≤69%).

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • 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 ≤49%).

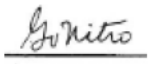
In most circumstances, these names are viewed as sufficiently different to minimize confusion. Exceptions to this would occur in circumstances where, for example, there are data that suggest a name with low similarity is nonetheless misinterpreted as a marketed product name in a prescription simulation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

Appendix A1: Description of FAERS

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. GoNitro Study (Conducted on September 3, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription: Refill(s): DEA No.	GoNitro Empty contents of 1-2 packs sublingually at onset of angina pain. May repeat every 5 minutes for up to 3 packs in 15 min Disp: 36

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

244 People Received Study
68 People Responded

Study Name: GoNitro

Total	24	18	26	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
GO NITRO	1	1	4	6
GOHITRO	1	0	0	1
GONITRO	21	13	22	56
GO-NITRO	0	3	0	3
GONITRO PACKETS	0	1	0	1
GORNITRO	1	0	0	1

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

No.	**Proposed name:** GoNitro **Established name:** nitroglycerin **Dosage form:** Powder for sublingual use **Strength(s):** 400 mcg **Usual Dose:** At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.	**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.	GENETRON 12	70	Product is not a drug. Product is a chemical (refrigerant).
2.	GoNitro	100	The subject of this review.

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

No.	Name	POCA Score (%)
1.	AKNETROL	56
2.	AMITRIL	50
3.	BONIKRAFT	50
4.	BOVAPRO Phon 71	59
5.	BRONCOTRON	50
6.	CALTRO	50
7.	CAPITROL	54
8.	CLINITAR	50
9.	COLYTROL	52
10.	CONCEPTROL	54
11.	DI-ATRO	60
12.	ECONTRA Phon 70	58
13.	EMETROL	50
14.	GADOBUTROL	51
15.	GANIDIN NR	56
16.	GENATON	57
17.	GENATUSS	52
18.	GENEXOL	50
19.	GENORA	56
20.	GENORA 1/50	56
21.	GENPRIN	52
22.	GENTRAN 40	58
23.	GENTRAN 70	58
24.	GLUMETZA	52
25.	(b) (4) ***	54
26.	GONAK	53
27.	GONAL-F RFF	54
28.	GONDAFON	52

No.	Name	POCA Score (%)
29.	GONIC	60
30.	GONIOSOFT	53
31.	GONIOSOL	60
32.	GRANIX	52
33.	GUANADREL	52
34.	GYNIX	50
35.	HABITROL	50
36.	KINERET	51
37.	LEVITRA	50
38.	NATROBA	52
39.	NITRO IV	56
40.	NITRO MACRO	50
41.	NITROCOT	50
42.	NITRONAL	50
43.	NITRONG	60
44.	NITRO-PAR	50
45.	NITROTAN	50
46.	OLEPTRO	52
47.	OMNITROPE	53
48.	ORENITRAM	50
49.	OSMITROL	58
50.	PACITRON	50
51.	PEDI-PRO Phon 72	60
52.	SONI-SLO	61
53.	TESTRO	50
54.	UNITHROID	51
55.	VI-ATRO	56
56.	VIVITROL	52
57.	VIVITROL ***	50
58.	VONTROL	62

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

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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.	COMMIT	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different, and the name GoNitro contains an extra syllable.
2.	COMPRO	62 (Phon 75)	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and the name GoNitro contains an extra syllable.
3.	DOMITOR (Phon 72)	61	The prefixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
4.	EQUETRO	53	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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**
5.	GABITRIL	60	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
6.	GANITE	54	Ganite is discontinued per Drugs@FDA, and deactivated per RedBook with no generic equivalent available. The third syllables of this name pair sound different, and the name GoNitro contains an extra syllable.
7.	GANI-TUSS NR	54	The suffixes of this name pair have sufficient orthographic differences. The third syllables of this name pair sound different, and the name Gani-Tuss NR contains two extra syllables.
8.	(b) (4) ***	67 ((b) (4))	The infixes and suffixes of this name pair have sufficient orthographic differences. The (b) (4) syllables of this name pair sound different.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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.	GENESA	52	The suffixes of this name pair have sufficient orthographic differences. The third syllable of this name pair sounds different.
10.	GENGRAF	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllable of this name pair sounds different, and the name GoNitro contains an extra syllable.
11.	GENOTROPIN	54	The suffixes of this name pair have sufficient orthographic differences. The forth syllable of this name pair sounds different, and the name Genotropin contains an extra syllable.
12.	GENPRIL	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different, and the name GoNitro contains an extra syllable.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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**
13.	GRANISETRON	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and the name Granisetron contains an extra syllable.
14.	GRANISOL	53	The suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
15.	MINITRAN	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
16.	MONIT	52	The prefixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and the name GoNitro contains an extra syllable.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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**
17.	MONIT LS	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and the name Monit LS contains an extra syllable.
18.	MONIT SR	62	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different, and the name Monit SR contains an extra syllable.
19.	NICOTROL	50	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
20.	NITREK	54	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and the name GoNitro contains an extra syllable.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**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**
21.	NITRO-DUR	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
22.	NITROL	62	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and the name GoNitro contains an extra syllable.
23.	NITROTAB	50	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first, second and third syllables of this name pair sound different.
24.	PHENETRON	57	The prefixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

No.	**Proposed name: GoNitro** **Established name: nitroglycerin** **Dosage form: Oral Powder** **Strength(s): 400 mcg** **Usual Dose:** **• At the onset of an attack, administer under the tongue. Repeat every 5 minutes as needed.** **• Do up to three (b) (4) within a 15-minute period. If chest pain persists, advise prompt medical attention.** **•May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack.**	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
25.	UNI-PRO	67 (Phon 71)	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.

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

No.	Name	POCA Score (%)
1.	BENADRYL	39
2.	BUDEPRION	38
3.	CAMPRAL	34
4.	CARBATROL	42
5.	CATAPRES	<20
6.	CHENIX	40
7.	CODEPREX	38
8.	COGNEX	34
9.	COMBIPRES	46
10.	COMPLERA	39
11.	CONCERTA	<20
12.	DANOCRINE	<20
13.	DANTRIUM	44
14.	DECADRON	36
15.	DEMEROL	<20
16.	DENAVIR	42
17.	DENDRID	42
18.	DI-METREX	42
19.	DOCEFREZ	38
20.	DUTOPROL	46
21.	ECONOPRED	46
22.	FENTORA	42
23.	GANTANOL	48
24.	Gaviscon	44
25.	GELATO	48
26.	GEMONIL	44
27.	GENOPTIC	42
28.	GERI-HYDROLAC	32
29.	GIAZO	42

No.	Name	POCA Score (%)
30.	GOLD BOND LOTION	34
31.	Golytely	44
32.	GONIOVISC	44
33.	KALETRA	46
34.	KANTREX	<20
35.	KEMADRIN	36
36.	KIONEX	40
37.	KONAKION	46
38.	MANNITOL 10%	48
39.	MANNITOL 15%	48
40.	MANNITOL 20%	48
41.	MANNITOL 25%	48
42.	MANNITOL 5%	48
43.	MEDIPREN	38
44.	MENOPUR	41
45.	METRA	44
46.	MINIPRESS	46
47.	MINIPRIN	46
48.	MONOPRIL	48
49.	MOVIPREP	47
50.	NEO-MEDROL	45
51.	NITROMIST	<20
52.	NITROPRESS	43
53.	NITROSTAT	42
54.	NORDITROPIN	45
55.	OBY-TRIM	48
56.	ONDANSETRON	46
57.	OXYTROL	48
58.	PEDI-DRI	46
59.	PEGINTRON	46

No.	Name	POCA Score (%)
60.	PIMTREA	42
61.	PREMPRO	<20
62.	QUDEXY	20
63.	STENDRA	40
64.	SYMMETREL	39
65.	TAMIFLU	38
66.	TEMPRA	38
67.	TYMTRAN	38
68.	VANIPLY	42
69.	VELETRI	<20
70.	ZADITOR	45
71.	ZANOSAR	42
72.	ZOHYDRO	48
73.	ZOMETA	46
74.	ZONATUSS	46

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

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4) ***	66	This name was identified in the RxNorm database. This name was denied under OSE RCM# 2009-1526. The product was approved under the name (b) (4) in OSE RCM# 2010-244.
2.	CORO-NITRO	68 (Ortho 72)	This name was identified in the RxNorm database. International product marketed in UK. Name for glyceryl trinitrate mucosal spray.
3.	(b) (4) ***	51	Name Entered by Safety Evaluator This name was not reviewed The product was approved under the name Movantik in OSE RCM# 2013-2226.
4.	GENTLE	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
5.	GONABREED	61	This name was identified in the RxNorm database. Veterinary product.
6.	(b) (4) ***	56	Name Entered by Safety Evaluator This name was denied under OSE RCM# 2012-1967. The product was approved under the name (b) (4) in OSE RCM# 2015-1120358.

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

No.	Name	POCA Score (%)
1.	ANADROL-50	50
2.	BENICAR	52
3.	BENZEPRO	55
4.	BONTRIL	56
5.	CLINPRO 5000	56
6.	COMETRIQ	56
7.	COMIXCO	51
8.	CONDRIN	52
9.	(b) (4) ***	54
10.	CONFFITS	50
11.	CONTRAVE	50
12.	DAYPRO	51
13.	DIPRO	54
14.	DOMEBORO	55
15.	DONNATAL	50
16.	EZ2GO ZERO	50
17.	KCENTRA	52
18.	KYNAMRO	57
19.	(b) (4) ***	50
20.	LIDOPRO	52
21.	LIPIDRO	50
22.	MENACTRA	50
23.	MONUROL	50
24.	NEUPRO	52
25.	NINLARO ***	52
26.	NORMIFLO	50
27.	NUPRO	52
28.	OMIDRIA	52

No.	Name	POCA Score (%)
29.	(b) (4) ***	60
30.	OTIPRIO ***	54
31.	PINE TAR	50
32.	(b) (4) ***	51
33.	QUIBRON	50
34.	SOMATREM	50
35.	(b) (4) ***	51
36.	UNIFERON	51
37.	UNIPRES	52
38.	UNIPRIM	52
39.	UNI-TREN	60
40.	VANATRIP	52
41.	ZONEGRAN	50
42.	ZUTRIPRO	50

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

No.	Name
1.	GINSENG
2.	GLYCOPYRROLATE
3.	GORDONS UREA 40

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/s/

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