CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209387Orig1s000

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:	March 2, 2017
Application Type and Number:	NDA 209387
Product Name and Strength:	Nipride RTU (sodium nitroprusside in 0.9% sodium chloride) 0.5 mg/mL
Total Product Strength:	50 mg/100 mL
Product Type:	Single-ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Exela
Panorama #:	2016-11813691
DMEPA Primary Reviewer:	Ashleigh Lowery, PharmD, BCCCP
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Nipride RTU, 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 proprietary name Nipride was previously marketed by Roche for NDA 017546. This product was sodium nitroprusside 50 mg powder, which required further dilution for intravenous administration. This product was discontinued and withdrawn on August 5, 1996.

Per the December 8, 2016 proprietary name submission, Exela has obtained the trademark Nipride. Exela now proposes the proprietary name Nipride RTU for sodium nitroprusside 50 mg/100 mL injection, which is ready for intravenous administration without further dilution.

1.2 PRODUCT INFORMATION

The following product information is provided in the December 8, 2016 proprietary name submission and December 14, 2016 proprietary name amendment.

- Intended Pronunciation: Nī - Prīd
- Active Ingredient: Sodium nitroprusside in 0.9% sodium chloride
- Indication of Use: Immediate reduction of blood pressure, producing controlled hypotension to reduce bleeding during surgery, and treatment of acute (b) (4) heart failure
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 50 mg/100 mL (0.5 mg/mL)
- Dose and Frequency: 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate
- How Supplied: 100 mL vial
- Storage: Store at 20°C to 25°C (68°F to 77°F). To protect from light, store in carton until it is used.

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 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

This proposed proprietary name is comprised of two words: the root name Nipride plus the modifier RTU. The Applicant indicated in their submission that the root name, Nipride, was derived from taking the first two letters of each syllable of Nitroprusside (i.e., "Ni" and "pr") and adding to them the last three letters ("ide"). The modifier RTU designates Ready-to-Use, which supports the product characteristic that the proposed product is pre-diluted and requires no further dilution, unlike currently marketed nitroprusside products. The Applicant also indicated that the modifier RTU avoids potential confusion with the previously marketed Nipride, which requires dilution prior to infusion.

Our evaluation of the root name Nipride noted that the proposed product sodium nitroprusside injection is the same active ingredient as the discontinued Nipride (sodium nitroprusside injection) and the products differ because the discontinued product required dilution and the proposed product does not. Additionally, we performed a FAERS search on December 15, 2016 and did not identify any medication errors related to name confusion with the root name Nipride (See section 2.2.7 below). Since new drugs have been introduced to the market since the brand product Nipride's discontinuation, we further evaluate the root name Nipride against new drug names introduced to the market since 1996 (See section 2.2.5 below).

With regard to the modifier RTU, we sent an information request to the applicant on December 19, 2016 inquiring if an evaluation was performed to assess the understanding of the modifier. They provided results of an informal survey of 12 pharmacists who responded that the term indicates "ready to use." We also noted that the modifier RTU was previously used in another product's proprietary name, Flagyl RTU (NDA 018353), to indicate "ready to use." This product was discontinued in 2006. A FAERS search performed on December 16, 2016 did not reveal any mediation error cases related to the use of the RTU (See section 2.2.5 below). Furthermore, in MediLexicon, "ready to use" is the first listed definition of RTU.[b] Other definitions of RTU listed in MediLexicon included real time ultrasound, reciprocal titer units, regional trauma unit, regular tobacco use, relative time unit, renal transplantation unit, and residual thyroid uptake (See Table 1 below). These terms do not indicate any obvious risk for medication errors related to the proprietary name. Lastly, the intended meaning of "ready to use" is not misleading as the product does not require further dilution or preparation prior to administration. For the aforementioned reasons, we do not object to the use of the modifier RTU for the proposed product.

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[a] USAN stem search conducted on December 16, 2016.

[b] http://www.medilexicon.com/abbreviations?search=RTU&target=abbreviations

Table 1. Use of "RTU"	
Product Name	**Definition**
Flagyl I.V. RTU*	Ready to Use
Medical Abbreviation†	
	Ready-To-Use Ready-To-Use Solution Real Time Ultrasonography Real Time Ultrasound Reciprocal Titer Units Regional Trauma Unit Regular Tobacco Use Relative Time Unit Renal Transplantation Unit Residual Thyroid Uptake

* Flagyl I.V. RTU in Plastic Container (metronidazole) Injection, NDA 018353, was discontinued by PFIZER in 2004.
† Source: http://www medilexicon.com/abbreviations?search=RTU&target=abbreviations, viewed 12/16/2016.

2.2.3 FDA Name Simulation Studies

Eighty-one (81) practitioners participated in DMEPA's prescription studies. Fifty-one practitioners responded with the correct interpretation "Nipride RTU". The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the verbal and written prescription studies.

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE December 22, 2016 e-mail, the Division of Cardiovascular and Renal Products (DCRP) forwarded concerns relating to the proposed proprietary name at the initial phase of the review. DCRP commented that the Applicant's intended meaning of "ready to use" for RTU does not readily come to mind, and they do not see a reason to include a formulation-indicating term. We acknowledged DCRP's comments but find the modifier acceptable as explained in Section 2.2.2.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 2 lists the number of names retrieved from our POCA search.[c] These names are organized as highly similar, moderately similar or low similarity for further evaluation.

[c] POCA search conducted on January 27, 2017 in version 4.0.

Table 2. Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	9
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	288
Low similarity name pair: combined match percentage score ≤54%	0

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

Our analysis of the 297 names contained in Table 2 determined 297 names will not pose a risk for confusion as described in Appendices C through H.

2.2.7 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Tables 3 and 4 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Nipride or the modifier RTU that would be relevant for this review.

Table 3. FAERS Search Strategy for Root name	
Search Date	December 16, 2016
Drug Name	Nipride [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR

	WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	Up to December 1, 2016

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

After individual review, four reports were not included in the final analysis for the following reasons: Cases unrelated to name confusion.

Following exclusions, the search yielded zero relevant cases.

Table 4. FAERS Search Strategy for Modifier	
Search Date	December 16, 2016
Drug Name	RTU [product verbatim]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List:** Preferred Terms: CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG ADMINISTRATION ERROR) DRUG DISPENSING ERROR DRUG PRESCRIBING ERROR INTERCEPTED DRUG DISPENSING ERROR INTERCEPTED DRUG PRESCRIBING ERROR INTERCEPTED MEDICATION ERROR MEDICATION ERROR PRODUCT NAME CONFUSION TRANSCRIPTION MEDICATION ERROR Lower Level Terms: INTERCEPTED PRODUCT SELECTION ERROR INTERCEPTED WRONG DRUG PRODUCT SELECTED INTERCEPTED WRONG DRUG SELECTED PRODUCT SELECTION ERROR WRONG DEVICE DISPENSED WRONG DRUG ADMINISTERED WRONG DRUG DISPENSED WRONG DRUG PRESCRIBED WRONG DRUG PRODUCT SELECTED

	WRONG DRUG SELECTED WRONG PRODUCT SELECTED
Date Limits	Up to December 1, 2016

The search yielded zero cases.

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 February 28, 2017. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DCRP March 2, 2017, they stated no additional concerns with the proposed proprietary name, Nipride RTU.

3 CONCLUSIONS

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, Nipride RTU, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your December 14, 2016 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 5*. 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 5- 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 6-8) 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 6).
- 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., route, frequency, dosage form) may be limited when the strength or dose

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

overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 7).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 8) 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 6. 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	**Y/N**	Do the syllables have different phonologic processes, such

	a different number or placement of upstroke/downstroke letters present in the names?		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 7: 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.

<table>
<tr><td></td><td colspan="2">

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

</td></tr>
<tr><td>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></td><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>
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Table 8: Low Similarity Name Pair Checklist (i.e., combined score is ≤54%).

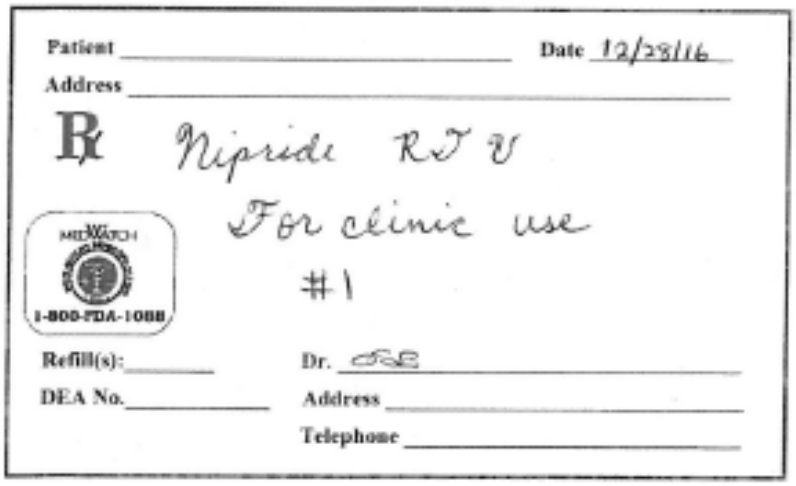
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity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

Appendix 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. Nipride RTU Study (Conducted on January 9, 2017)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order: Nipride RTU Start infusion at 0.3 mcg/kg/min. Titrate to SBP <160. Do not exceed 10 mcg/kg/min. Outpatient Prescription:  Patient _____ Date 12/28/16 Address _____ ℞ Nipride RTU For clinic use #1 MEDWATCH 1-800-FDA-1088 Refill(s): _____ Dr. _____ DEA No. _____ Address _____ Telephone _____	Nipride RTU. For clinic use. Dispense #1.

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

302 People Received Study
81 People Responded

Study Name: Nipride RTU

Total	28	28	25	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
NIPRID RTU	0	2	0	2
NIPRIDE	4	0	1	5
NIPRIDE RTU	0	1	0	1
NIPRIDE ETU	0	1	0	1
NIPRIDE RDV	1	0	0	1
NIPRIDE RJ U	1	0	0	1
NIPRIDE RJU	1	0	0	1
NIPRIDE RJV	8	0	0	8
NIPRIDE RTU	7	20	24	51
NIPRIDE RTV	5	0	0	5
NIPRODE RTV	1	0	0	1
NYPRIDE RTU	0	4	0	4

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

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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.	Inderide Inderide-40/25 Inderide-80/25	70	Brand discontinued but generic is available. The prefixes and infixes of this name pair have sufficient orthographic differences. The first letters "N" and "I" are different. Nipride has a downstroke in the infix versus Inderide has an upstroke in the infix. The first and second syllables of this name pair sound different and Inderide contains an extra syllables. When considering the modifiers "40/25," "80/25," and "RTU," there are additional orthographic and phonetic differences.
2.	Mitride	82	Brand discontinued with no generic equivalent available. Drug is not listed in Drugs@FDA. Last pricing availability in Micromedex Redbook is from 1996.
3.	Neuprolide	70	This is a secondary proposed proprietary name that was never reviewed. The request for proprietary name was withdrawn and a new name was submitted. The application received a complete response.
4.	Nifurzide	70	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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.	Nipride	100	Brand Nipride was discontinued in 1996. We noted that the proposed Nipride RTU injection contains the same active ingredient as the discontinued Nipride (sodium nitroprusside for injection), just that the dosage forms differ. Additionally, the proposed RTU modifier will help to differentiate the different dosage form between the two products. Thus, the risk of confusion is minimized because both products share the same active ingredient.
6.	Piperine	73	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first letters "N" and "P" are different. Nipride has an upstroke in the suffix and Piperine does not. The first syllables of this name pair sound different and Piperine contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic different and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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.**
7.	Nitro-Bid	70	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. Nipride has a downstroke in the infix and Nitro-Bid has an upstroke in the infix. Also, Nipride has one upstroke in the suffix and Nitro-Bid has two upstroke letters in the suffix. The second syllables of this name pair sound different and Nitro-Bid contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
8.	Syprine	72	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first letters "N" and "S" are different and Syprine has a downstroke in the prefix not seen in Nipride. Nipride has an upstroke in the suffix versus Syprine does not. The first syllables of this name pair sound different.
9.	Tiapride	76	International product marketed in Germany.
10.	Unipres	70	Brand discontinued with no generic equivalent available.

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.	Addaprin	60
2.	Biltricide	56
3.	Budeprion	55

No.	Name	POCA Score (%)
4.	Capozide Capozide 25/15 Capozide 25/25	56
5.	Ciprodex	56
6.	Dendrid	67
7.	Deprizine	66
8.	Desonide	56
9.	Diprolene	63
10.	Diprosone	62
11.	Epimide 50	58
12.	Genprin	60
13.	Iopromide	60
14.	Mafenide	56
15.	Moviprep	56
16.	Nasalide	59
17.	Nephramine	64
18.	Neupro	56
19.	Nicomide	60
20.	Niferex	56
21.	Niferex-150	56
22.	Nitric Oxide	55
23.	Nitrogen	60
24.	Nutrilipid Nutrilipid 10% Nutrilipid 20%	55
25.	Omnicide	58
26.	Omnipred	69
27.	Phentride	69
28.	Priadel	55
29.	Privine	58
30.	Ridiprin	62
31.	Supred	56
32.	Teniposide	60

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:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	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.	Amiloride	55	The prefixes and infixes of this name pair have sufficient orthographic differences and Amiloride contains 2 additional letters. The first and second syllables of this name pair sound different and Amiloride contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
2.	Amisulpride	58	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Amisulpride contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
3.	Anagrelide	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Anagrelide contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
4.	Capozide 50/15 Capozide 50/25	56	Brand discontinued but generic is available. The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Capozide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
5.	Cuprimine	55	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different and Cuprimine contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
6.	Daranide	58	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Daranide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
7.	Desipramine	56	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Desipramine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
8.	Diprivan	64	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different and Diprivan contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
9.	Glimepiride	60	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and glimepiride contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
10.	Glipizide	59	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and glipizide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
11.	Ibuprin	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Ibuprin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
12.	Imipramine	60	The prefixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Imipramine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
13.	Leuprolide	56	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different and Leuprolide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
14.	Medipred	64	Brand discontinued but generic is available. The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Medipred contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
15.	Medipren	64	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Medipren contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	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**
16.	Meperidine	64	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Meperidine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
17.	Mepriam	62	Brand discontinued but generic is available. The prefixes and suffixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different and Mepriam contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
18.	Microzide	61	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Microzide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
19.	Millipred	60	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Millipred contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	POCA Score (%)	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
20.	Minipress	60	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Minipress contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
21.	Miniprin	64	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Miniprin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
22.	Naprelan	60	The suffixes of this name pair have sufficient orthographic differences. Naprelan contains an extra syllable "lan" that provides sufficient phonetic differences. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables. Although Naprelan and Nipride RTU share similar numerical strength (Naprelan 500 mg vs. Nipride RTU 50 mg/100 mL), the risk of confusion is minimized because the doses do not overlap (Naprelan 375 mg, 500 mg, 750 mg; or # tablets vs. Nipride RTU 0.3 mcg/kg/min to 10 mcg/kg/min).

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	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**
23.	Naprosyn	56	The suffixes of this name pair have sufficient orthographic differences. Naprosyn contains an extra syllable "syn" that provides sufficient phonetic differences. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
24.	Naproxen	56	The suffixes of this name pair have sufficient orthographic differences. Naproxen contains an extra syllable "xen" that provides sufficient phonetic differences. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
25.	Neofrin	59	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Neofrin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
26.	Neoprofen	56	The suffixes of this name pair have sufficient orthographic differences. The second syllables sound different and Neoprofen contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	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**
27.	Nephramine 5.4%	64	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nephramine contains an extra syllable. When considering the modifiers "RTU" and "5.4%," there are additional orthographic and phonetic differences.
28.	Nesiritide	64	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nesiritide contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
29.	Nevirapine	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nevirapine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
30.	Nicardipine	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nicardipine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
31.	Nifedipine	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nifedipine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
32.	Nipent	58	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables. Nipent is dosed every other week vs. Nipride RTU is continuous dosing to desired effect.
33.	Nipride RTU	64	This name is the subject of this review.
34.	Nitrek	66	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	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**
35.	Nitrendipine	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitrendipine contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
36.	Nitro IV	69	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitro IV contains two extra syllables. When considering the modifier "RTU," Nipride RTU contains an extra syllable.
37.	Nitro-Bid Iv	56	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitro-Bid IV contains three extra syllables. When considering the modifier "RTU," the third, fourth, and fifth syllables sound different.
38.	Nitro-Dur	62	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitro-Dur contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
39.	Nitrol	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables.
40.	Nitro-Par	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitro-Par contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
41.	Nitropress	58	This is the RLD for the subject of this review. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitropress contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
42.	Nitroprusside	58	This is the active ingredient for the subject of this review. The infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitroprusside contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
43.	Nitrotab	56	Brand discontinued but generic is available. The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitrotab contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
44.	Nitro-Time	61	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nitro-Time contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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.	Np Thyroid	60	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables sound different and Np Thyroid contains two extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains an extra syllable.
46.	Nuplazid	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nuplazid contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
47.	Nuprin	69	Brand Nuprin is discontinued but generic ibuprofen is available. The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables. Nuprin is dosed as 1 tablet, 2 tablets, or as needed, which is unlikely to overlap with Nipride RTU dosed in # mcg/kg/min to the desired effect.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
48.	Nutropin	58	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nutropin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
49.	Nydrazid	60	The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nydrazid contains an extra syllables. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
50.	Nylidrin	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different and Nylidrin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
51.	Panheprin	55	Brand discontinued but generic is available. The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Panheprin contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
52.	Pimozide	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Pimozide contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
53.	Prinzide	64	Brand discontinued but generic is available. The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
54.	Triglide	56	Brand discontinued but generic is available. The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables.
55.	Unipen	58	Brand discontinued but generic is available. The prefixes, infixes, and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Unipen contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.
56.	Veripred	60	The prefixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different and Veripred contains an extra syllable. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains two extra syllables.

No.	**Proposed name:** Nipride RTU **Established name:** Sodium nitroprusside in 0.9% sodium chloride **Dosage form:** Injection **Strength(s):** 50 mg/100 mL (0.5 mg/mL) **Usual Dose:** 0.3 mcg/kg/min to 10 mcg/kg/min, titration to desired effect or maximum infusion rate	**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**
57.	Vistide	56	The prefixes and infixes of this name pair have sufficient orthographic differences. The first syllables of this name pair sound different. When considering the modifier "RTU," Nipride RTU has additional orthographic differences and contains three extra syllables.

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

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

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

No.	Name	POCA Score (%)	Failure preventions
1.	Abinide	56	This is a secondary proposed proprietary name. The primary proposed name was denied and the ANDA was approved and marketed using the established name only (amantadine hydrochloride).
2.	Alizapride	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
3.	Amprid	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Anipryl	60	Veterinary product
5.	Aphedrid	56	Brand discontinued with no generic equivalent available.

No.	Name	POCA Score (%)	Failure preventions
6.	Aprindine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Atridine	56	Brand discontinued with no generic equivalent available.
8.	Bentiromide	55	Product discontinued with no generic available.
9.	Bepridil	60	Brand discontinued with no generic equivalent available.
10.	Berkaprine	55	International product marketed in the United Kingdom.
11.	Biperiden	65	Brand discontinued with no generic equivalent available.
12.	Bornaprine	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
13.	Boron Nitride	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
14.	Bromopride	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
15.	Caprin	56	International product marketed in Australia.
16.	Cetrimide	56	Product is not a drug. It is a cleaning agent.
17.	Cinitapride	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
18.	Cipro I.V.	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
19.	Cisapride	66	Brand discontinued with no generic equivalent available.
20.	Clebopride	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
21.	Dipro	60	Root name for an international product (Dipro AS) marketed in Brazil.
22.	Dipropizine	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
23.	Emeside	56	International product marketed in the United Kingdom.
24.	Entaprin	60	Brand discontinued with no generic equivalent available.

No.	Name	POCA Score (%)	Failure preventions
25.	Epipram	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
26.	Eprident	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
27.	Fenspiride	63	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
28.	Gyburide	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
29.	Imipramide	65	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
30.	Ivercide	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
31.	Lisuride	62	International product marketed in Germany.
32.	Luride	57	Brand discontinued with no generic equivalent available.
33.	Mefruside	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
34.	Minaprine	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
35.	Minizide	64	Brand discontinued with no generic equivalent available.
36.	Mosapride	64	Brand discontinued with no generic equivalent available.
37.	Naprofen	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Neophryn	56	International product marketed in the United Kingdom.
39.	Neo-Predef	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
40.	Neotrizine	55	Brand discontinued with no generic equivalent available.
41.	Nephrox	58	Brand discontinued with no generic equivalent available.
42.	Nervine	66	International product marketed in Canada.

No.	Name	POCA Score (%)	Failure preventions
43.	Nexcede	56	Brand discontinued with no generic equivalent available.
44.	Niaprazine	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
45.	Niclocide	58	Brand discontinued with no generic equivalent available.
46.	Nifedpine	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
47.	Nitarsone	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
48.	Nitrados	60	International product marketed in Ireland, New Zealand, Singapore, Thailand, and the United Kingdom.
49.	Nitrite Ion	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
50.	Nitrocine	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
51.	Nitrocot	57	Brand discontinued with no generic equivalent available.
52.	Nitrogard	58	Brand discontinued with no generic equivalent available.
53.	Nitrong	61	Brand discontinued with no generic equivalent available.
54.	Nitrotan	57	Product is not a drug. It is a swimming pool and aquarium cleaning product.
55.	Nitrozone	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
56.	Nobrium	58	International product marketed in Hungary, Ireland, Italy, Netherlands, United Kingdom, Spain, and Switzerland.
57.	Norimode	56	International product marketed in South Africa and the United Kingdom.
58.	Normozide	56	Brand discontinued with no generic equivalent available.
59.	Novapurine	58	This is a secondary proposed proprietary name and the product was approved under proprietary name Purixan.

No.	Name	POCA Score (%)	Failure preventions
60.	Nycopren	56	International product marketed in Austria, Belgium, Denmark, Finland, Greece, Netherlands, Switzerland, and the United Kingdom.
61.	Nydrane	63	International product marketed in the United Kingdom.
62.	Operidine	58	International product marketed in Australia and the United Kingdom.
63.	Oprisine	56	International product marketed in the United Kingdom.
64.	Ornipressin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
65.	Pentigide	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
66.	Phenoperidine	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
67.	Preferid	56	International product marketed in Belgium, Ireland, Italy, Netherlends, Norway, Sweden, Switzerland, and the United Kingdom.
68.	Prinize	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
69.	Pripsen	55	International product marketed in Ireland and the United Kingdom.
70.	Remoxipride	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
71.	Riboprine	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
72.	Sulpiride	61	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
73.	Tetra-ide	64	Brand discontinued with no generic equivalent available.
74.	Tiropramide	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
75.	Triblide	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
76.	Tridrane	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
77.	Uniparin	62	International product marketed in Australia and the United Kingdom.
78.	Uniprim	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
79.	Veralipride	57	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
80.	Vesprin	58	Brand discontinued with no generic equivalent available.
81.	Xipamide	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

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 (%)
1.	Almitrine	58
2.	Amidrine	68
3.	Android	64
4.	Android 10	64
5.	Android 25	64
6.	Android 5	64
7.	Android-10	64
8.	Android-25	64
9.	Android-F	56
10.	Anefrin	59
11.	Aniline	57
12.	Antipyrine	64
13.	Aprodine	59
14.	Benzedrine	56
15.	Bepreve	60
16.	B-Fedrine	60
17.	Biofreeze	56
18.	Budipine	57
19.	Centrine	62

[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	POCA Score (%)
20.	Cephradine	56
21.	Ceprotin	56
22.	Cetiri-D	59
23.	Citrate	55
24.	Danaparoid	58
25.	Danocrine	58
26.	Depade	56
27.	Deplin	57
28.	Depopred	56
29.	Deproist	61
30.	Diaphine	60
31.	Diar-Aid	56
32.	Didrex	58
33.	Difemerine	56
34.	Differin	58
35.	Dimine	58
36.	Diperodon	64
37.	Dipyrone	67
38.	Ditropan	56
39.	Diupres	64
40.	Diupres-250	64
41.	Diupres-500	64
42.	Donnapine	57
43.	Drize	56
44.	Edecrin	56
45.	Empirin	55
46.	Endrate	55
47.	Enovid-E	58
48.	Enovid-E 21	58
49.	Enpresse-21	59
50.	Enpresse-28	59
51.	Ephedrine	62
52.	Epidrin	58
53.	Epifrin	56
54.	Epinephrine	60
55.	Eyephrine	56
56.	Gepefrine	58
57.	Inapsine	61
58.	Innopran	60
59.	Iopidine	57
60.	Isoprene	57
61.	Key-Pred	56
62.	Menrium 10-4	58

No.	Name	POCA Score (%)
63.	Menrium 5-2	58
64.	Menrium 5-4	58
65.	Mepron	61
66.	Meprozine	62
67.	Meptid	55
68.	Metramid	57
69.	Metro I.V.	58
70.	Metrodin	57
71.	Midodrine	61
72.	Midrin	62
73.	Migrend	60
74.	Milprem-200	62
75.	Milprem-400	62
76.	Minirin	58
77.	Mipen	55
78.	Mitran	56
79.	Morphine	56
80.	Muprocin	56
81.	Myfedrine	56
82.	Omnitrope	56
83.	Ordrine	56
84.	Paludrine	55
85.	Paredrine	59
86.	Pediapred	58
87.	Pedi-Pro	55
88.	Perlite	56
89.	Phenyldrine	56
90.	Picrate	58
91.	Piperazine	58
92.	Pramine	57
93.	Prefrin	56
94.	Prepadine	56
95.	Proin	56
96.	Proline	57
97.	Propine	58
98.	Pyrite	60
99.	Ranitidine	56
100.	Ritodrine	56
101.	Septrin	56
102.	Serine	57
103.	Sparine	64
104.	Spermine	57
105.	Sudrine	62

No.	Name	POCA Score (%)
106.	Suphedrine	55
107.	Suprane	56
108.	Synephrine	64
109.	Tacrine	62
110.	Tetterine	58
111.	Tildren	56
112.	Timpron	60
113.	Tisopurine	56
114.	Uni-Pro	61
115.	Unithroid	62
116.	Uni-Tren	66
117.	Zentrip	56

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/s/

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