CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207318Orig1s000

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)

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Date of This Review:	November 5, 2015
Application Type and Number:	NDA 207318
Product Name and Strength:	Nuplazid (pimavanserin) Tablets, 17 mg
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Acadia Pharmaceuticals, Inc.
Panorama #:	2015-5619460
DMEPA Primary Reviewer:	Deborah Myers, RPh, MBA
DMEPA Team Leader:	Danielle Harris, PharmD, BCPS

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Nuplazid, 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. However, the submitted external study was dated November 20, 2013, and it is the same study that was previously considered during a previous review of this name. Since the external study was conducted, the proposed strength and dosing have changed for this product.

1.1 REGULATORY HISTORY

The Applicant previously submitted the proposed proprietary name, Nuplazid (IND 068384), on November 27, 2013. The Division of Medication Error Prevention and Analysis (DMEPA) found the name, Nuplazid, acceptable in OSE Review #2013-16613, dated April 29, 2014. However, this previous review was based on (b) (4) (b) (4). The strength and dosing have changed with this submission for review.

1.2 PRODUCT INFORMATION

The following product information is provided in the September 1, 2015 proprietary name submission.

- Intended Pronunciation: noo pla' zid
- Active Ingredient: pimavanserin
- Indication of Use: for the treatment of psychosis associated with Parkinson's disease
- Route of Administration: oral
- Dosage Form: tablet
- Strength: 17 mg
- Dose and Frequency: two 17 mg tablets once daily (i.e., 34 mg once daily)
- How Supplied: 60-count bottles intended for commercial use

  14-count bottles intended for physician samples
- Storage: Store at 25°C (77°F); excursions permitted between 15°C and 30°C (59° and 86°F) [See USP controlled Room Temperature].

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 Psychiatry Products (DPP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

The Applicant did not provide a derivation or intended meaning for the proposed name, Nuplazid in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 FDA Name Simulation Studies

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

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 20, 2015, the Division of Psychiatry Products (DPP) 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 from the external name study conducted by (b) (4).

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%	108

[1]USAN stem search conducted on September 18, 2015.

[2] POCA search conducted on September 18, 2015.

Low similarity name pair: combined match percentage score ≤49%	8

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

The proposed product, Nuplazid will be available in a strength of 17 mg. Since this 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 Nuplazid that were not identified in POCA, and found to have an overlap in strength with Nuplazid.

Table 1A. eDRLS Search Results	**POCA score**
Nisoldipine – is available as an 8.5 mg, 17 mg, 25.5 mg, and 34 mg extended-release oral tablet indicated for the treatment of hypertension and dose as one tablet once daily. The usual maintenance dosage is 17 mg to 34 mg once daily.	34

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

Our analysis of the 119 names contained in Table 1 and Table 1A determined all 119 names will not pose a risk for confusion as described in Appendices C through H.

2.2.8 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on November 2, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DPP on November 5, 2015, they stated no additional concerns with the proposed proprietary name, Nuplazid.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE project manager, at 240-402-5035.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 1, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair 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.

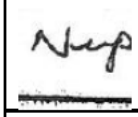
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length 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 B: Prescription Simulation Samples and Results

Figure 1. Nuplazid Study (Conducted on October 2, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order:  Outpatient Prescription: 	Nuplazid 17 mg Take 2 tablets by mouth once daily. Dispense #60

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
68 People Responded

Study Name: Nuplazid

Total	24	21	23	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
NEPLAZID	0	0	1	1
NEPLOZID	0	0	1	1
NEUPLASIC	0	1	0	1
NEUPLASID	0	1	0	1
NEUPLASIT	0	1	0	1
NEUPLAZID	0	3	0	3
NEWPLAZID	0	3	0	3
NIPLOZID	0	0	2	2
NUPAZID	1	0	0	1
NUPLAGID	2	0	0	2
NUPLASID	0	8	0	8
NUPLAZID	7	3	4	14

NUPLAZIND	1	0	0	1
NUPLOGID	2	0	0	2
NUPLOYID	2	0	0	2
NUPLOZID	6	0	15	21
NUPLOZOID	1	0	0	1
NUQLOGID	1	0	0	1
NYLOZID	1	0	0	1
NYUPLASID	0	1	0	1

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

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily (34 mg once daily)	**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.	Nuplazid***	100	Name is the subject of this review.
2.	Nydrazid	72 (Phonetic score of 76)	The infixes (pla vs dra) of this name pair have sufficient orthographic differences. The first (Noo vs Nye) and second (pla vs dra) syllables of this name pair sound different. Nydrazid has been discontinued, however generic isoniazid is currently marketed as both a 100 mg oral tablet and 100 mg/mL intramuscular injection. There is no overlap in strength between these products (Nuplazid will be available in 17 mg vs. isoniazid 100 mg and 100 mg/mL). There is no overlap in dosage. Nuplazid is dosed as two 17 mg (34 mg) tablets once daily vs. isoniazid which is dosed 5mg/kg up to 300 mg once daily in a single dose, or 15 mg/kg up to 900 mg/day, two or three times a week.

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.	Nutrilipid	60
2.	Nutrilipid 10%	60
3.	Nutrilipid 20%	60
4.	Nplate	56
5.	Nubain	52
6.	Cisplatin	50
7.	Neupogen	50

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:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**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.	Nexafed	61	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
2.	Nulecit	59	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
3.	Tubizid	59	The prefixes and infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
4.	Nitro-bid	58 (Phonetic score of 71)	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
5.	Neoloid	57	The infixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
6.	Neutragard	57	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
7.	Zuplenz	57	The suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Nuplazid contains an extra syllable.

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**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.	Neutracett	56 (Phonetic score of 77)	The infixes and suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different.
9.	Norpramin	56	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
10.	Nuprin	55	The suffixes of this name pair have sufficient orthographic differences. The second syllables of this name pair sound different, and Nuplazid contains an extra syllable.
11.	Naglazyme	54	The suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
12.	Nalfed	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Nuplazid contains an extra syllable.
13.	Naprelan	54	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
14.	Neptazane	54	The suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
15.	Nipride	54	The suffixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Nuplazid contains an extra syllable.
16.	Laniazid	53	The prefixes/infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Laniazid contains an extra syllable.
17.	Plavix	53	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 Nuplazid contains an extra syllable.
18.	Delazinc	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
19.	Duoplant	52	The prefixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
20.	Neocidin	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Neocidin contains an extra syllable.
21.	Neo-fradin	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Neo-fradin contains an extra syllable.

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**POCA Score (%)**	**Prevention of Failure Mode** **In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names**
22.	Nexavir	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
23.	Nexplanon	52	The suffixes of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
24.	Nitric acid	52	The infixes and suffixes of this name pair (Nuplazid vs Nitric Acid) have sufficient orthographic differences. The first, second, third syllables of this name pair sound different, and Nitric acid contains an extra syllable.
25.	Novafed A	52	The infixes and suffixes of this root name pair, Nuplazid vs. Novafed, have sufficient orthographic differences. The first, second, and third syllables of the root name pair, Nuplazid vs. Novafed, sound different. In addition, Novafed A contains a modifier making this name pair sound different when spoken, if included.
26.	Noxafil	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
27.	Nutropin	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
28.	Nuvaring	52	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**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**
29.	Plasmin	52	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 Nuplazid contains an extra syllable.
30.	Isoniazid	51	The prefixes and infixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different, and Isoniazid contains two extra syllables.
31.	Neo-polycin	51	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different, and Neo-polycin contains two extra syllables.
32.	Namzaric	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
33.	Natazia	50	The infixes of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different, and Natazia contains an extra syllable.
34.	Neulasta	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
35.	Neutra-phos	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.

No.	**Proposed name:** Nuplazid **Established name:** pimavanserin **Dosage form:** tablet **Strength(s):** 17 mg **Usual Dose:** two 17 mg tablets once daily	**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**
36.	Nulojix	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
37.	Nutr-e-sol	50	The infixes and suffixes of this name pair have sufficient orthographic differences. The second 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.	Neutrexin	48
2.	Prevacid	48
3.	Naproxen	43
4.	Nupercainal	42
5.	Novolog	40
6.	Nucynta	40
7.	Nisoldipine	34
8.	Nasonex	32
9.	Luvox	17

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.	Neoplatin	66 (Phonetic score of 72)	International product marketed in Spain.
2.	Duoplavin***	62 (Phonetic score of 75)	This proposed proprietary name was found acceptable by DMEPA (OSE# 2007-5212). The current Application status is Withrawn, dated February 25, 2009.
3.	Norplant	61	Brand discontinued with no generic equivalent available (per RedBook).
4.	Noctamid	60	International product marketed in Belgium, Germany, Greece, Ireland, Netherlands, New Zealand, Spain, Switzerland, South Africa, Italy, and Portugal.
5.	Nasabid	59	Brand discontinued with no generic equivalent available (per RedBook).
6.	Novafed	58	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
7.	(b) (4)***	57	The proposed proprietary names, (b) (4) (b) (4), were withdrawn by the Applicant October 14, 2011 (OSE# 2011-3375). A new proposed propriatary name, (b) (4) was subimitted November 9, 2011 (OSE# 2011-3965), however this name was denied on November 22, 2011 based on a DDMAC objection. The Application is pending (currently in Complete Response) and no new names have been submitted.
8.	Colazide	56	International product marketed in the UK.
9.	Diclozip	56 (Phonetic score of 72)	International product marketed in the UK.
10.	Neugranin***	56	Proposed proprietary name found unacceptable by DMEPA (OSE# 2010-1746). A new proposed proprietary name, Egranli***, was submitted October 25, 2011 and found acceptable on April 17, 2012 (OSE# 2011-4076). The Application is currently inactive.
11.	Niclocide	56	Brand discontinued with no generic equivalent available (per RedBook).
12.	Placidyl	56	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
13.	Muprocin	55 (Phonetic score of 74)	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
14.	Niaprazine	55	International product marketed in France and Italy.
15.	Nucofed	55	Brand discontinued with no generic equivalent available (per RedBook).
16.	Virazid	55	International product formerly marketed in Spain.
17.	Nudal HD	54	Brand discontinued with no generic equivalent available (per RedBook).
18.	Naus-aid	53	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
19.	Nalacet	52	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
20.	Neilfed	52	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
21.	Noctesed	52	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.

No.	Name	POCA Score (%)	Failure preventions
22.	Nolahist	52	Brand discontinued with no generic equivalent available (per RedBook).
23.	Narasin	51	Veterinary product.
24.	Nasofed	51	Brand discontinued with no generic equivalent available (per RedBook).
25.	Nitrados	51	International product marketed in New Zealand, Singapore, and Thailand and formerly marketed in Ireland.
26.	Nylidrin	51	Brand discontinued with no generic equivalent available (per RedBook). A powder formulation is available for compounding purposes, however, no solid dosage forms are available.
27.	Tolazil	51	Veterinary product.
28.	Gliclazide	50	International product marketed in Canada and India, among numerous others.
29.	Neo-predef	50	Veterinary product.
30.	Nexgard	50	Veterinary product.
31.	Nialamide	50	International product marketed in Belgium and France.
32.	Nifurzide	50	International product marketed in Mexico and France.
33.	Nitrogard	50	Brand discontinued with no generic equivalent available (per RedBook).

No.	Name	POCA Score (%)	Failure preventions
34.	Norlutin	50	Brand discontinued with no generic equivalent available (per RedBook).
35.	Novrad	50	Brand discontinued with no generic equivalent available (per RedBook).
36.	Placidex	50	International product formerly marketed in the UK.
37.	Sulfazin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
38.	Tolazine	50	Veterinary product.
39.	Urizid	50	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 notable spelling, orthographic and phonetic differences.

No.	Name	POCA Score (%)
1.	Dilaudid	56
2.	Dilaudid-5	56
3.	Aplenzin	54
4.	Durafed	54
5.	(b) (4) ***	54
6.	Enplus-HD	54
7.	Metramid	54
8.	Bucladin-S	53

No.	Name	POCA Score (%)
9.	Dolobid	53
10.	Acyanid	52
11.	Bubbli-pred	52
12.	Buclizine	52
13.	Palm acid	52
14.	Sulfabid	52
15.	Uracid	52
16.	Disalcid	51
17.	Monocid	51
18.	Smoflipid***	51
19.	Labid	50
20.	Macrobid	50
21.	(b) (4) ***	50
22.	Silafed	50
23.	Sinus Aid	50
24.	Sudafed	50
25.	Tabloid	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.	Ammonium Lactate
2.	Argentum 17 Special Order
3.	Articulatio interphalangea 17 Special Order
4.	Atrovent
5.	AtroventHFA
6.	Aurum 17 Special Order
7.	Becca
8.	berkley and jensen clearlax
9.	Body Series Invisible Solid Deodorant and Antiperspirant

No.	Name
10.	Bronchi 17 Special Order
11.	care one clearlax
12.	Cinis Quercus 17 Special Order
13.	clear lax
14.	clear laxative
15.	Clearlax
16.	Cuprum 17 Special Order
17.	dg health clearlax
18.	equaline clearlax
19.	equate clear lax
20.	EZ2go
21.	EZ2go Stimu-Lax
22.	family wellness laxative
23.	Fulton Street Market Clearlax
24.	GAVILAX
25.	gentle lax
26.	GlycoLax
27.	Good Neighbor Pharmacy ClearLax
28.	Good Sense Clear Lax
29.	harris teeter clearlax
30.	health mart clearlax
31.	healthy accents clear lax
32.	healthylax
33.	ImproVue
34.	Jasper 17 Special Order
35.	kirkland signature laxaclear
36.	Laxative
37.	Leader Clear Lax
38.	Lubas
39.	Magnesium Citrate Saline Laxative

No.	Name
40.	Maximum Strength Wart Remover with Salicylic Acid
41.	Members Mark clearlax
42.	MiraLAX
43.	NATURA-LAX
44.	Old Spice Fresh
45.	Old Spice Game Day
46.	Old Spice Invisible After Hours
47.	Old Spice Original
48.	Old Spice Playmaker
49.	Old Spice Red Zone Collection
50.	Old Spice Red Zone Collection Invisible Pure Sport
51.	Old Spice Red Zone Collection Swagger
52.	Olivenite 17 Special Order
53.	PEG 3350
54.	PEN Prep
55.	Periogel
56.	Polyethylene Glycol (3350)
57.	Polyethylene Glycol 3350 NF
58.	Polyethylene Glycol 3350, NF Powder for Solution, Laxative
59.	Preferred Plus ClearLax
60.	purelax
61.	QuitaCallos
62.	Secret Outlast Clear Clean Lavender
63.	ShopRite Clear Laxative
64.	Simply Right clearLAX
65.	Smart Sense Clearlax
66.	SmartMouth
67.	smooth lax
68.	Stannum 17 Special Order
69.	Sular

No.	Name
70.	sunmark clearlax
71.	Topcare ClearLax
72.	up and up powderlax
73.	Urea
74.	Verruguin
75.	Verucide Physician Formula
76.	VIRCIN Advanced wart treatment
77.	VISCO SHIELD

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/s/

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11/05/2015

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11/05/2015