CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761025Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	January 14, 2015
Application Type and Number:	BLA 761025
Product Name and Strength:	Praxbind (idarucizumab) Injection, 2.5 g/50 mL (50 mg/mL)
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals, Inc.
Submission Date:	December 22, 2014
Panorama #:	2014-46038
DMEPA Primary Reviewer:	Neil Vora, PharmD, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Praxbind (BLA 761025). DMEPA previously found the name acceptable in OSE Review #2014-26202[1], dated November 14, 2014

1.1 PRODUCT INFORMATION

The following product information is provided in the December 22, 2014 proprietary name submission.

- Intended Pronunciation: praks' bīnd
- Active Ingredient: Idarucizumab
- Indication of Use: Idarucizumab is proposed to be indicated for use in patients treated with dabigatran who have uncontrolled bleeding or life-threatening bleeding requiring urgent intervention, and in patients who require emergency surgery/procedures when rapid reversal of the anticoagulant effects of dabigatran is required.
- Route of Administration: Intravenous
- Dosage Form: Solution for intravenous injection
- Strength: 50 mg/mL
- Dose and Frequency: The usual dosage of idarucizumab is 5 grams administered consecutively as two 2.5 gram vials as bolus injection or infusion. Repeat dosing with idarucizumab is not supported by clinical data and is not intended.
- How Supplied: Carton including 2 single use vials each containing 2.5 grams of idarucizumab.
- Storage: Idarucizumab vials must be refrigerated at 2°C to 8°C (36°F to 46°F) and should be kept in the outer carton to protect from light until the time of use. Idarucizumab vials should not be frozen or shaken. As the solution does not contain preservatives, any unused portion should be discarded.

1.2 MISBRANDING ASSESSMENT

On January 5, 2015, The Office of Prescription Drug Promotion (OPDP) determined that the proposed name does not misbrand the proposed product. On January 13, 2015 DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

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[1] Vora N. Proprietary Name Review for Praxbind (IND 112278). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Nov 14. 35p. OSE RCM No. 2014-26202.

1.3 SAFETY ASSESSMENT

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 3) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2014-26202 that have orthographic and phonetic similarities to the proposed name Praxbind. Our POCA search did not identify any new names that represent a potential source of drug name confusion. Additionally, we re-evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Furthermore, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The January 9, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

As a result, we maintain that the name, Praxbind is acceptable.

2 CONCLUSIONS

The proposed proprietary name is acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

2.1 COMMENTS TO THE APPLICANT

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

3 REFERENCES

1. Vora N. Proprietary Name Review for Praxbind (IND 112278). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2014 Nov 14. 35p. OSE RCM No. 2014-26202.

2. ***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.

3. ***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.

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

/s/

NEIL H VORA
01/14/2015

YELENA L MASLOV
01/14/2015

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 14, 2014
Application Type and Number:	IND 112278
Product Name and Strength:	Praxbind (idarucizumab) Injection, 2.5 g/50mL (50 mg/mL)
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Boehringer Ingelheim Pharmaceuticals, Inc.
Submission Date:	August 20, 2014
Panorama #:	2014-26202
DMEPA Primary Reviewer:	Neil Vora, PharmD, MBA
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Praxbind, 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. Boehringer Ingelheim did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the August 20, 2014 proprietary name submission.

- Intended Pronunciation: praks' bīnd
- Active Ingredient: Idarucizumab
- Indication of Use: Idarucizumab is proposed to be indicated for use in patients treated with dabigatran who have uncontrolled bleeding or life-threatening bleeding requiring urgent intervention, and in patients who require emergency surgery/procedures when rapid reversal of the anticoagulant effects of dabigatran is required.
- Route of Administration: Intravenous
- Dosage Form: Solution for intravenous injection
- Strength: 50 mg/mL
- Dose and Frequency: The usual dosage of idarucizumab is 5 grams administered consecutively as two 2.5 gram vials as bolus injection or infusion. Repeat dosing with idarucizumab is not supported by clinical data and is not intended.
- How Supplied: Carton including 2 single use vials each containing 2.5 grams of idarucizumab.
- Storage: Idarucizumab vials must be refrigerated at 2°C to 8°C (36°F to 46°F) and should be kept in the outer carton to protect from light until the time of use. Idarucizumab vials should not be frozen or shaken. As the solution does not contain preservatives, any unused portion should be discarded.

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 does not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) 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 indicated in their submission that the proposed name, Praxbind, is derived from its specific binding affinity for Pradaxa (dabigatran). 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.

2.2.4 FDA Name Simulation Studies

One hundred practitioners participated in DMEPA's prescription studies. Fifty seven practitioners interpreted the name correctly as Praxbind. The remaining 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.

In the written outpatient study, 12 of the 57 participants correctly interpreted the prescription. Common misinterpretations include interpreting the "ax" for "ox" and "pr" for "ps."

In the written inpatient study, 31 of the 57 participants correctly interpreted the prescription. Common misinterpretations include interpreting the "in" for "en" and "axb" for "axy."

In the voice study, 14 of the 57 participants correctly interpreted the prescription. Common misinterpretations include "ax" for "ex," "bi" for "ti," "bi" for "fi," "xb" for "xp" and "bi" for "br."

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

2.2.5 Comments from Other Review Disciplines at Initial Review

In response to the OSE, September 15, 2014 e-mail, the Division of Hematology Products (DHP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.6 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

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[1]USAN stem search conducted on October 14, 2014.

[2] POCA search conducted on September 29, 2014.

or low similarity for further evaluation. Table 1 also includes names identified from the FDA Prescription Simulation.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined, phonetic, orthographic match percentage score ≥70%	1
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	190
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 191 names contained in Table 1 determined that all 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 Hematology Products (DHP) via e-mail on November 5, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on November 12, 2014, they stated no additional concerns with the proposed proprietary name, Praxbind.

3 CONCLUSIONS

The proposed proprietary name, Praxbind is acceptable.

If you have further questions or need clarifications, please contact Sarah Harris, OSE project manager, at 240-402-4774.

3.1 COMMENTS TO THE APPLICANT

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

A request for proprietary name review for Praxbind should be submitted once the NDA is submitted.

If any of the proposed product characteristics as stated in your August 20, 2014 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.

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 DNCE. OPDP or DNCE 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 DNCE 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 do 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 **<u>with</u>** 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	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?

	scripted? • Do the suffixes of the names appear dissimilar when scripted?	

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. Praxbind Study (Conducted on September 5, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Praxbind 5 grams IV over 30 minutes x1 Outpatient Prescription: Praxbind Bring to Clinic #2	Praxbind Bring to clinic Dispense #2

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received Study
100 People Responded

Study Name: Praxbind

Total	31	31	38	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ARISTADA	0	0	1	1
PRACINE	0	1	0	1
PRACSBINE	0	1	0	1
PRACSTEIN	0	1	0	1
PRAXBAIN	0	1	0	1
PRAXBAN	0	1	0	1
PRAXBEND	0	0	5	5
PRAXBIND	12	14	31	57
PRAXBINE	0	1	0	1

PRAXBRIND	0	1	0	1
PRAXCIDE	0	1	0	1
PRAXFIND	0	3	0	3
PRAXPINE	0	1	0	1
PRAXSTEIN	0	1	0	1
PRAXSTINE	0	1	0	1
PRAXYBIND	0	0	1	1
PREXBIND	0	1	0	1
PROXBIND	18	0	0	18
PSAXBIND	1	0	0	1

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

No.	Proposed name: Praxbind Strength(s): 2.5 g/50 mL Usual Dose: 5 grams administered consecutively as two 2.5 gram vials as bolus injection or infusion	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Praxbind ***	100	Proposed proprietary name subject of this review

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

No.	Proposed Name	POCA Score (%)
1.	Prascend	68
2.	Perox-Aid	62
3.	Puroxcin	60
4.	Priftin	58
5.	Pred Mild	57
6.	Proxigel	56
7.	Prevacid	55
8.	Pramoxine	54
9.	Pro Dine 5000C	54
10.	Proactiv	54
11.	Prohist DM	54
12.	Prolex D	54
13.	Promectin	54
14.	Protex D	54
15.	Pulexn DM	54
16.	Treximet	53
17.	Prax	53

18.	Paxofen	52
19.	Pepsodent	52
20.	Podactin	52
21.	Prascion	52
22.	Pravastatin	52
23.	Prefrin-A	52
24.	Prodrin	52
25.	Abraxane	51
26.	Prezcobix ***	51
27.	Pepcid RPD	50
28.	Pherazine DM	50
29.	Poly Tan D	50
30.	Polytan D	50
31.	Praluent ***	50
32.	Precedex	50
33.	ProDenRx	50
34.	Proprinal	50
35.	ProQuad	50
36.	Prosed	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: Praxbind Strength(s): 2.5 g/50 mL Usual Dose: 5 grams administered consecutively as two 2.5 gram vials as bolus injection or infusion	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.	Procanbid	66	The infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
2.	Roxybond	66	The proposed name has two syllables while this name contains three syllables. The prefix and infix have sufficient orthographic and phonetic differences.
3.	Draxxin	62	The prefix and suffix of this name pair has sufficient orthographic differences. The last syllables in both names give the names a distinctly different sound when spoken.
4.	Primaxin	62	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
5.	Prolex PD	62	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
6.	Prandin	61	The suffix of this name pair has sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
7.	Magnebind	60	The prefix and infix of this name pair has sufficient orthographic differences.

			Both names have a different number of syllables. The first two syllables of Magnebind distinctly sound different from the proposed name when spoken.
8.	Magnebind 250/300	60	The prefix and infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The first two syllables of Magnebind distinctly sound different from the proposed name when spoken. This name also contains a modifier.
9.	Magnebind 400/200	60	The prefix and infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The first two syllables of Magnebind distinctly sound different from the proposed name when spoken. This name also contains a modifier.
10.	Magnebind-200	60	The prefix and infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The first two syllables of Magnebind distinctly sound different from the proposed name when spoken. This name also contains a modifier.
11.	Magnebind-300	60	The prefix and infix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The first two syllables of Magnebind distinctly sound different from the proposed name when spoken. This name also contains a modifier.
12.	Plasbumin	59	The infix suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The last two syllables of Plasbumin sound distinctly different when spoken.
13.	Plasbumin-20	59	The infix suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The last two syllables of Plasbumin sound distinctly different when spoken. This name also contains a modifier.
14.	Plasbumin-25	59	The infix suffix of this name pair has sufficient

			orthographic differences. Both names have a different number of syllables. The last two syllables of Plasbumin sound distinctly different when spoken. This name also contains a modifier.
15.	Plasbumin-5	59	The infix suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. The last two syllables of Plasbumin sound distinctly different when spoken. This name also contains a modifier.
16.	Prostin VR	59	The suffix of this name pair has sufficient orthographic differences. The last syllable of both names sound distinctly different when spoken. This name also contains a modifier.
17.	Prevident	58	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
18.	Proben C	58	The prefix and suffix of this name pair has sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
19.	Prolixin	58	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
20.	Pyrlex PD	58	The prefix and infix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
21.	Calcibind	57	The prefix and infix of this name pair have sufficient orthographic differences.

			Both names have a different number of syllables. The first two syllables in both names give the names a distinctly different sound when spoken.
22.	Prandimet	57	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
23.	Peroxin A	57	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and third syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
24.	Peroxin A 10	57	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and third syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
25.	Prazosin	57	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The last two syllables in both names give the names a distinctly different sound when spoken.
26.	Prudoxin	57	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
27.	Miraxid	56	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and last syllables in both names give the names a distinctly different sound when spoken.
28.	Pregnitude	56	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All

			the syllables in both names give the names a distinctly different sound when spoken.
29.	Plasmin	56	The prefix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
30.	Prolex DM	56	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
31.	Periactin	56	The prefix, infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
32.	Pricortin	56	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
33.	Primaxin IM	56	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and last syllable in Primaxin gives the name a distinctly different sound when spoken. This name also contains a modifier.
34.	Primaxin IV	56	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and last syllable in Primaxin gives the name a distinctly different sound when spoken. This name also contains a modifier.
35.	Prohist CD	56	The suffixes of this name pair have sufficient orthographic differences. All syllables in both names distinctly sounds different when spoken. This name also contains a modifier.
36.	Prolastin	56	The infix and suffix of this name pair have sufficient

			orthographic differences. Both names have a different number of syllables. The first and last syllable of Prolastin sound distinctly different when spoken.
37.	Prostascint	56	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
38.	Protid	55	The suffixes of this name pair have sufficient orthographic differences. All syllables in both names distinctly sounds different when spoken.
39.	Prefrin	54	The suffixes of this name pair have sufficient orthographic differences. All syllables in both names distinctly sounds different when spoken.
40.	Purixan	54	The prefix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
41.	Principen	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
42.	Principen 125	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
43.	Principen 250	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly

			different sound when spoken. This name also contains a modifier.
44.	Principen 500	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
45.	Probenecid	54	The suffixes of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
46.	Protropin	54	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
47.	Presgen	53	The suffixes of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
48.	Procysbi	53	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
49.	Paroxetine	52	The suffixes of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first, second and fourth syllables of Paroxetine sound distinctly different when spoken.
50.	Pentrax Gold	52	The prefix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
51.	Pramine	52	The suffixes of this name pair have sufficient

			orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
52.	Propulsid	52	The infix and suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
53.	Predamide	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and second syllables of Predamide sound distinctly different when spoken.
54.	Preludin	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
55.	Presamine	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
56.	ProQuin	52	The suffixes of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken.
57.	Prostigmin	52	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
58.	Prostin E2	52	The suffixes of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
59.	Paloxin	51	The prefix and suffix of this name pair have sufficient

			orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
60.	Pediatan D	51	The prefix, infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
61.	Privigen	51	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
62.	ProctoKit	51	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
63.	Pretz-D	51	The suffix of this name pair has sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
64.	Protein C	51	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
65.	Ceraxon	50	The prefix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The first and third syllables of Ceraxon give the names a distinctly different sound when spoken.
66.	Paraplatin	50	The infix and suffix of this name pair have sufficient orthographic differences.

			Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
67.	Paxidorm	50	The suffixes of this name pair have sufficient orthographic differences. Both names have a different number of syllables. The second and third syllables of Paxidorm give the names a distinctly different sound when spoken.
68.	Pramimil	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
69.	Prednicen M	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.
70.	Premarin	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
71.	Procapan	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
72.	Profloxacin	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
73.	Promolaxin	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly

			different sound when spoken.
74.	Prothiaden	50	The infix and suffix of this name pair have sufficient orthographic differences. Both names have a different number of syllables. All the syllables in both names give the names a distinctly different sound when spoken.
75.	P-Tann D	50	The infix and suffix of this name pair have sufficient orthographic differences. All the syllables in both names give the names a distinctly different sound when spoken. This name also contains a modifier.

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

No.	Name	POCA Score (%)
1.	N/A	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.	(b) (4)	58	This is a secondary proposed name. Product approved under the primary name Rybix ODT.
2.	Prohistine-D	58	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
3.	Prolactin	57	Name Identified in RxNorm. Unable to find product

			characteristics in commonly used databases.
4.	Duraxin	56	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
5.	Pri-Cortin 50	56	Product discontinued: no generics available
6.	Propranidid	56	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
7.	Prehist D	55	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
8.	Profender	54	Strictly a veterinary product used to treat worms in felines.
9.	ProZinc	54	Strictly for veterinary use only.
10.	Progabide	53	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
11.	Platosin	52	International product marketed in Turkey, UK, Austria, Belgium, Czech Republic, Greece, Indonesia, Japan, Netherlands, and South Africa.
12.	Preferid	52	International product marketed in Italy and Norway.
13.	(b) (4)	52	This proposed proprietary name was denied by OPDP on January 6, 2011 in OSE RCM #2010-2449.
14.	Prepadine	52	International product only

			marketed in the UK.
15.	Prepulsid	52	International product only marketed in Hong Kong, Argentina, Australia, Austria, Belgium, Czech Republic, Denmark, Finland, France, Ireland, Israel, Italy, New Zealand, Netherlands, Norway, South Africa, Chile, Mexico, Portugal, Spain, Sweden, Switzerland, Thailand, UK, Canada, Brazil, Singapore and China.
16.	Pridinol	52	International product only marketed in Brazil
17.	Pripsen	52	International product only marketed in UK and Ireland.
18.	Prohibit	52	Product discontinued: no generics available
19.	Prosaid	52	International product only marketed in UK
20.	Protamines		Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
21.	Paraffin	51	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
22.	Platinum	51	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
23.	Prohistine DM	51	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
24.	Protein S	51	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.

25.	Proteins	51	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
26.	Pro-Vent	51	International product only marketed in Ireland and UK
27.	Placidex	50	International product only marketed in UK
28.	Platinex	50	International product only marketed in Germany, Israel, Italy and UK
29.	Pre Sed	50	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
30.	Pressimmune	50	International product only marketed in UK
31.	Prezatide	50	Name Identified in RxNorm. Unable to find product characteristics in commonly used databases.
32.	Prolex DMX	50	Product discontinued: no generics available

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

No.	Name	POCA Score (%)
1.	Hextend	57
2.	Ciproxin	56
3.	Maximum D3	56
4.	Triactin DM	56
5.	(b) (4)	55
6.	Brovex PBD	54
7.	Coricidin D	54
8.	Drixomed	54

9.	Naproxen	54
10.	Reprexain	54
11.	Saxenda ***	54
12.	Tranxene-SD	54
13.	Traxene SD	54
14.	Trexbrom	54
15.	Roxiprin	53
16.	Trioxin	53
17.	Brexidol	52
18.	Brovex PD	52
19.	Crixivan	52
20.	Drexophed	52
21.	Flexbumin	52
22.	Fragmin	52
23.	Freshmint	52
24.	Morphabond ***	52
25.	OxyBlend	52
26.	Recofen D	52
27.	Respbid	52
28.	(b) (4)	52
29.	Claritin-D	51
30.	Nexphen PD	51
31.	Triactin	51
32.	Apixaban	50
33.	Axitinib	50
34.	Carboxine 12 D	50
35.	Carboxine D	50
36.	Eprident	50
37.	Fexmid	50
38.	Forbaxin	50
39.	Maxiphen CD	50

40.	Maxiphen DM	50
41.	Ricobid D	50
42.	Tranzene	50
43.	Triptided	50
44.	Tri-Statin	50
45.	Trixaicin	50
46.	Truxcillin	50
47.	Vibramycin-D	50
48.	Viractin	50

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/s/

NEIL H VORA
11/14/2014

YELENA L MASLOV
11/17/2014