CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

207026Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW 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:	August 05, 2014
Application Type and Number:	NDA 207026
Product Name and Strength:	Phoxillum BK4/2.5 and Phoxillum B22K4/0 Hemofiltration and Hemodiafiltration Solution
Product Type:	Multi-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gambro Lundia AB
Submission Date:	July 23, 2014
Panorama #:	2014-25916 and 2014-25917
DMEPA Primary Reviewer:	Jean Olumba, MD, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD
Associate Director:	Lubna Merchant, PharmD, M.S.

Contents

1 INTRODUCTION

DMEPA previously reviewed and denied the proposed proprietary names, "Phoxilium BK4/2.5" and "Phoxilium B22K4/0", in OSE Review# 2014-17170 and 2014-17171 (See DARRTS NDA 207026 Proprietary name review, dated June 30, 2014). The basis of our denial was the root name (b) (4) We did not identify any other safety concerns with names Phoxilium BK4/2.5 and Phoxilium B22K4/0. Also, the modifiers "BK4/2.5" and "B22K4/0" did not pose any safety concerns and were found acceptable.

On June 26, 2014, a telephone conference was held with Gambro Lundia AB to communicate DMEPA's concerns with the proposed root name, Phoxilium, and to provide the Applicant with possible modifications to the spelling of the name that could be viable alternatives including the spelling option "Phoxillum" (See DARRTS NDA 207026 General advice letter, dated June 30, 2014).

On July 23, 2014, the Applicant submitted the proposed proprietary name "Phoxillum BK4/2.5" and "Phoxillum B22K4/0" for review.

2 RESULTS

2.1 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's promotional assessment of the proposed name.

2.2 SAFETY ASSESSMENT

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Safety Analysis of the Proposed Proprietary Name

Our previous orthographic and phonetic analysis did not find Phoxilium BK4/2.5 and Phoxilium B22K4/0 to look or sound similar to any existing drug names. The currently proposed names, Phoxillum BK4/2.5 and Phoxillum B22K4/0, changed from the dotted letter "i" to the upstroke letter "l" in the 6th position. This change does not alter the overall shape, orthographic appearance or phonetic sound of the proposed root name

[1]USAN stem search conducted on July 28, 2014.

because there is already an upstroke letter “l” in the 5th position of the previous root name Phoxilium and maintained in the currently proposed Phoxillum. Additionally, we had previously considered that the letter “i” may be misinterpreted as the letter “l” in our previous review. Therefore, the change from the letter “i” to the letter “l” in the 6th position did not alter our previous finding that the names do not look or sound similar to any existing drug names. In addition, we did not identify any new safety concerns with the names, Phoxillum BK4/2.5 and Phoxillum B22K4/0.

3 CONCLUSIONS

DMEPA finds the proposed proprietary names, “Phoxillum BK4/2.5” and “Phoxillum B22K4/0”, acceptable from both a promotional and safety perspective.

If you have further questions or need clarifications, please contact Karen Bengtson, OSE project manager, at 301-796-3338.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary names, Phoxillum BK4/2.5 and Phoxillum B22K4/0, and have concluded that these names are acceptable.

If any of the proposed product characteristics as stated in your July 23, 2014 submission are altered, the name must be resubmitted for review.

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

/s/

JEAN C OLUMBA
08/05/2014

CHI-MING TU
08/05/2014

KELLIE A TAYLOR on behalf of LUBNA A MERCHANT
08/05/2014

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

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Center for Drug Evaluation and Research (CDER)

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Date of This Review:	June 30, 2014
Application Type and Number:	NDA 207026
Product Name and Strength:	Phoxilium B22K4/0 Hemofitration and Hemodiafiltration Solution
Product Type:	Multi-Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Gambro Lundia AB
Submission Date:	April 2, 2014
Panorama #:	2014-17171
DMEPA Primary Reviewer:	Jean Olumba, MD, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Phoxilium B22K4/0, from a safety and promotional perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant did not submit an external name study for this proposed proprietary name.

1.1 PRODUCT INFORMATION

The following product information is provided in the April 2, 2014 proprietary name submission.

Intended Pronunciation: Not intended to differ from the way it is written.

Active Ingredient: Calcium/ Magnesium/ Sodium/ Potassium/ Sodium bicarbonate/ Dibasic sodium phosphate

Indication:

1. As a replacement solution in Continuous Renal Replacement Therapy (CRRT) to replace plasma volume removed by ultrafiltration and to correct electrolytes and acid-base imbalances.
2. In case of drug poisoning when CRRT is used to remove filterable substances.

Route: Administered into the extracorporeal circuit before (pre-dilution) and/or after the hemofilter or hemodiafilter (post-dilution).

Dosage Form: Solution

Strengths:

1000 mL of clear electrolyte solution (small compartment A) contains (g):

Active ingredients	Phoxilium B22K4/0
Calcium chloride. $2H_2O$	0
Magnesium chloride. $6H_2O$	3.05

1000 mL of clear buffer solution (large compartment B) contains (g):

Active ingredients	Phoxilium B22K4/0
Sodium chloride	6.95
Sodium bicarbonate	2.21
Potassium chloride	0.314
Sodium phosphate. $2H_2O$	0.187

After Reconstitution of compartment A and B

1000 mL of clear reconstituted solution contains:

in mEq/L except where noted	Phoxilium B22K4/0
Calcium	0
Bicarbonate	22
Potassium	4
Magnesium	1.5
Sodium	140
Phosphate HPO_4^{2-}	1 mmol/L
Chloride	122
Theorectical Osmolarity	290 mOsm/L

Dose and Frequency: The mode of therapy, solute formulation, flow rate and length of therapy should be selected by the physician responsible for managing treatment depending on the clinical condition of the patient as well as the patient's fluid, electrolyte and acid-base balance.

How Supplied: 5000 mL PVC bag composed of two compartments. 250 mL small compartment and 4750 mL large compartment. The compartments are separated by a red transparent pin. The bag is overwrapped with a transparent overwrap.

Storage: 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 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 PROMOTIONAL ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined the proposed name is acceptable from a promotional perspective. DMEPA and the Division of Cardiovascular and Renal Products (DCRP) concurred with the findings of OPDP's promotional 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

The proposed product is an electrolyte solution and not a quaternary ammonium derivative. Proprietary names should not incorporate

2.2.2 Components of the Proposed Proprietary Name

The proposed name is comprised of multiple words: the root name Phoxilium, and the modifier B22K4/0.

The Applicant indicated in their submission that (b) (4) Additionally for the modifier B22K4/0: the B22 stands for a lower bicarbonate concentration (22 instead of 32), K stands for Potassium, the number 4 corresponds to potassium amount, and the number 0 highlights the absence of calcium.

We note that a similar modifiers "B22GK 4/0" with the same meaning has already been in use for another drug product, Prismasol B22GK 4/0 solution. Table 2 lists the Prismasol product line per Drugs@FDA. Since there is precedence of similar modifiers like "B22K4/0" for electrolyte solutions used for continuous renal replacement therapy, we do not object to the use of this modifier in the proposed name.

Table 2. Primasol product line[4]

Product Names	Product Names	Product Names
Prismasol B22GK 2/0	Prismasol BGK 0/2.5	Prismasol BK 0/0
Prismasol B22GK 2/2.5	Prismasol BGK 2/0	Prismasol BK 0/0/1.2
Prismasol B22GK 4/0	Prismasol BGK 2/3.5	Prismasol BK 0/3.5
Prismasol B22GK 4/2.5	Prismasol BGK 4/0	Prismasol BK 4/2.5
	Prismasol BGK 4/0/1.2	
	Prismasol BGK 4/2.5	
	Prismasol BGK 4/3.5	

2.2.3 FDA Name Simulation Studies

104 practitioners participated in DMEPA's prescription studies. The interpretations did not overlap with any currently marketed products nor did the misinterpretations sound or look similar to any currently marketed products or any products in the pipeline. Fifteen participants in the verbal study interpreted the first syllable "Pho" as "Fo". Appendix B contains the results from the verbal and written prescription studies.

[4] Drugs@FDA. Search results for "Primasol". Accessed 6/25/2014 online at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.SearchAction&SearchTerm=prismasol&SearchType=BasicSearch&#totable

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, April 11, 2014, the Division of Cardiovascular and Renal Products (DCRP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Table 3 lists the number of names with the combined orthographic and phonetic score of ≥50% retrieved from our POCA search organized as highly similar, moderately similar or low similarity for further evaluation.

Table 3. 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%	114
Low similarity name pair: combined match percentage score ≤49%	0

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

Our analysis of the 116 names contained in Table 2 determined 116 names would not pose a risk for confusion as described in Appendices C through G.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Cardiovascular and Renal Products (DCRP) via e-mail on June 27, 2014 to notify DCRP of our denial of the proposed proprietary name, Phoxilium B22K4/0, (b) (4)

3 CONCLUSIONS

The proposed proprietary name is acceptable from a promotional perspective but not acceptable from a safety perspective. Therefore, the decision to deny the name will be communicated to the Applicant/Sponsor via letter (See ***Section 3.1).***

If you have further questions or need clarifications, please contact Karen Bengtson, OSE project manager, at 301-796-3338.

3.1 COMMENTS TO THE APPLICANT

We have completed our review of the proposed proprietary name, Phoxilium B22K4/0, and have concluded that this name is unacceptable based on the concerns we have with the root name, Phoxilium. We did not identify any concerns with the "B22K4/0" modifier at this time that would render the use of that modifier unacceptable. Our concerns with Phoxilium are as follows:

[5] PDUFA pilot project proprietary name review concept paper. September 2008. http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072229.pdf

[6] Guidance for industry: Best practices in developing proprietary names for drugs. Draft Guidance May 2014. http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM398997.pdf

REFERENCES

(b) (4)

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 considers the promotional and safety aspects of a proposed proprietary name.

1. **Promotional Assessment**: For prescription drug products, the promotional review of the proposed name is conducted by OPDP. For over-the-counter (OTC) drug products, the promotional review of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if they are overly fanciful, so as to misleadingly imply unique effectiveness or composition, as well as to assess whether they contribute to overstatement of product efficacy, minimization of risk, broadening of product indications, or making of unsubstantiated superiority claims. 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. [7]

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

	Affirmative answers to these questions indicate a potential area of concern.
Y/N	Does the name have obvious Similarities in Spelling and Pronunciation to other Names?
Y/N	Are there Manufacturing Characteristics in the Proprietary Name?
Y/N	Are there Medical and/or Coined Abbreviations in the Proprietary Name?
Y/N	Are there Inert or Inactive Ingredients referenced in the Proprietary Name?
Y/N	Does the Proprietary Name include combinations of Active Ingredients
Y/N	Is there a United States Adopted Name (USAN) Stem in the Proprietary Name?
Y/N	Is this the same Proprietary Name for Products containing Different Active Ingredients?
Y/N	Is this a Proprietary Name of a discontinued product?

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

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. Based on our root cause analysis of post marketing experience errors, we find the expression of strength and dose, which is often located in close proximity to the drug name itself on prescriptions and medication orders, is an important factor in mitigating or potentiating confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion is limited (e.g., route, frequency, dosage form, etc.).

- For highly similar names, there is little that can mitigate a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are likely to be rejected by FDA. (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, 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 (e.g., route, frequency, dosage form, etc.) to mitigate confusion may be limited when the strength or dose overlaps. FDA will review these 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 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 (See Table 5).

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 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 (see Step 1 of the Moderately Similar Checklist).			
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 have a higher potential for confusion and should be evaluated further (see Step 2). For single strength products, also consider circumstances where the strength may not be expressed. For any combination drug products, 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: o 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. o Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. o Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion between 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 there are data that suggest a name with low similarity might be vulnerable to confusion with your proposed name (for example, misinterpretation of the proposed name as a marketed product 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. Phoxilium B22K4/0 Study (Conducted on April 24, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Phoxilium B22K4/0 Send 3L to oncology clinic every day.	Phoxilium B22K4/0 Bring to clinic # 1
Outpatient Prescription: Phoxilium B22K4/0 Bring to clinic #1	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

study name: phoxilium b22k4 0

as of date 6/18/2014

274 people received study

104 people responded

study name: phoxilium b22k4 0

total	34	29	41	
interpretation	**outpatient**	**voice**	**inpatient**	**total**
baccilium b22k4/0	0	1	0	1
bockzillium b22k4/0	0	1	0	1
boxilium b22k4/0	0	2	0	2
boxillium b22k4-0	0	1	0	1
boxzillium	0	1	0	1
facvilian b22q4-0	0	1	0	1
fosbillion b224-0	0	1	0	1
fosvilium b22k4-0	0	1	0	1
foxicillium b22k4/0	0	1	0	1
foxilium	0	1	0	1
foxilium b22k4/0	0	1	0	1
foxilium b22k4-0	0	1	0	1
foxillium	0	1	0	1
foxillium b22k4/0	0	1	0	1
foxzilium b22k4/0	0	2	0	2
foxzillium	0	2	0	2
foxzillium b22k4-0	0	1	0	1
foxzillium d22k4/0	0	1	0	1
fozillium	0	1	0	1
phocilium	0	0	1	1
phoxili	1	0	0	1
phoxilimm	1	0	0	1
phoxilinan bxxk	1	0	0	1

phoxilinan bzzk4/0	1	0	0	1
phoxilinem bzzk4/0	1	0	0	1
phoxilinim b22k4/0	1	0	0	1
phoxilinium bzzk4/0	1	0	0	1
phoxilinm	2	0	0	2
phoxilinm b22k4/0	1	0	0	1
phoxilinn bzzk4/0	1	0	0	1
phoxilinson b22k4/0	1	0	0	1
phoxiliren b22k 4/0	0	0	1	1
phoxiliren b22k4/0	0	0	1	1
phoxilium	2	0	11	13
phoxilium bzzk	1	0	0	1
phoxilium b22 k 4/0	0	0	1	1
phoxilium b22k	0	1	3	4
phoxilium b22k 4/0	1	0	3	4
phoxilium b22k a/o	0	0	1	1
phoxilium b22k4/0	11	0	9	20
phoxilium b22-k4/0	0	1	0	1
phoxilium b22k4/o	0	0	1	1
phoxilium b22ka/)	0	0	1	1
phoxilium bzzk	2	0	0	2
phoxilium bzzk4/0	2	0	0	2
phoxiliun	0	0	1	1
phoxilom	1	0	0	1
phoxiluin	0	0	3	3
phoxiluin b22k4/0	0	0	1	1
phoxilum b22k/0	0	0	1	1
phoxilunsn b22k4/0	1	0	0	1
phoxilven b22k 4/0	0	0	1	1
phoxilvin b22k4/0	0	0	1	1
phoxlilium	1	0	0	1
phoxzilium b22k4/0	0	1	0	1

voxilium	0	1	0	1
voxilium b22k4/0	0	1	0	1
voxilium b22k4-0	0	1	0	1
voxillium v224/0	0	1	0	1

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

No.	**Proposed name:** Phoxilium B22K4/0 **Usual Dose:** selected by the physician, depending on the clinical condition of the patient.	POCA Score (%)	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Or** **Failure prevention reasons**
1.	Phoxilium B22K4/0	80	This is the proprietary name under this review.
2.	Phoxilium BK4/2.5	80	The proposed proprietary name under review OSE RCM# 2014-17170.

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

No.	Name	POCA Score (%)
1.	Dexilant	50
2.	Doxylamine	50
3.	Exelderm	50
4.	Maxiflu DM	51
5.	Methoxsalen	50
6.	Nexium	52
7.	Oxylone	51
8.	Oxyprim	50
9.	Paxil CR	52
10.	Paxil	54
11.	Penicillin	52
12.	Penicillin-2	52
13.	Pentoxil	50
14.	Phenflu DM	54
15.	Phrenilin	50
16.	Piroxicam	53
17.	Polycillin	52
18.	Proglycem	52

No.	Name	POCA Score (%)
19.	Pyridium	54
20.	Valium	50

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

No.	**Proposed name:** Phoxilium B22K4/0 **Usual Dose:** selected by the physician, depending on the clinical condition of the patient.	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.	Focalin	54	The prefix and infix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
2.	Hexalen	52	The prefix and suffix of this name pair have sufficient orthographic differences. The first syllable of this name pair sounds different.
3.	Oxacillin	52	The prefix of this name pair has sufficient orthographic differences. The second syllable of this name pair sounds different, and Oxacillin contains an extra syllable.
4.	Oxilan 300	57	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair sounds different.
5.	Oxilan 350	57	The prefix of this name pair has sufficient orthographic differences. The first syllable of this name pair sounds different.
6.	Photofrin	51	The infix and suffix of this name pair have sufficient orthographic differences. The second and third syllables of this name pair sound different.
7.	Prometrium	51	The infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
8.	Psyllium	63	The infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
9.	P.A.S. Sodium	58	The infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Phoxilium contains an extra syllable

No.	**Proposed name:** Phoxilium B22K4/0 **Usual Dose:** selected by the physician, depending on the clinical condition of the patient.	**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**
10.	Paxipam	58	The prefix and suffix of this name pair have sufficient orthographic differences. The first and third syllables of this name pair sound different.
11.	Petrolatum	56	The prefix and infix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different. Petrolatum contains an extra syllable.
12.	Prodium	52	The infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different. Phoxilium contains an extra syllable
13.	Pyrvinium	52	The prefix and infix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
14.	Bretylium	51	The prefix and infix of this name pair have sufficient orthographic differences. The first and second syllables of this name pair sound different.
15.	Tocilizumab	50	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, third, fourth, and fifth syllables of this name pair sound different. Tocilizumab contains two extra syllables.
16.	Totacillin	55	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.
17.	Totacillin-N	55	The prefix, infix, and suffix of this name pair have sufficient orthographic differences. The first, second, and third syllables of this name pair sound different.

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.	Motilium	66	International product marketed in several countries.
2.	Paskalium	66	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. NDA 009395 has been in withdrawn FR effective status since 2007.
3.	Prilium***	66	Name identified in Names Entered by SE database. Unable to find product characteristics in commonly used drug database.
4.	Moxilin	64	International product marketed in several countries.
5.	Penoxsulam	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
6.	Paxidorm	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
7.	Sterillium	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
8.	Doxy Lemmon	57	Name identified in RxNorm database. Drugs @FDA database indicated this is a discontinued product.
9.	Amprolium	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
10.	Cit Calcium	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
11.	Potassium	56	Name identified in RxNorm database. Although there are many Potassium containing products, no Potassium (without "Chloride" or "Aminosalicylate") product can be identified.
12.	propicillin	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
13.	proxifen***	56	Name identified in Names Entered by SE database. Unable to find product characteristics in commonly used drug database.
14.	Staphcillin	56	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. NDA 050117 has been in withdrawn FR effective status since 9/29/1995 and ANDA 061449 has been in withdrawn FR effective status since 3/16/2000.
15.	Thulium	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
16.	Hexocyclium	55	Name identified in RxNorm database. Drugs @FDA database indicated that this is a discontinued product with no generic equivalent available. NDA 010599 has been in withdrawn FR effective status since 9/5/1996.
17.	Oxitropium	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
18.	Dexium	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
19.	Doxacurium	54	Name identified in Drugs @FDA database. This is a discontinued product with no generic equivalent available. NDA 019946 has been in withdrawn FR effective status since 4/18/2012
20.	Floxin I.V.	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
21.	Floxacillin	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
22.	Ioxilan	54	Product is marketed with the trade name 'Oxilan'. Generic equivalent product is not available
23.	Octylonium	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
24.	Oxeladin	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
25.	Photocil	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
26.	Pipoxolan	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
27.	Poloxalene	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
28.	Pondocillin	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
29.	Ponoxylan	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
30.	Prifinium	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

No.	Name	POCA Score (%)	Failure preventions
31.	(b) (4)***	54	Name identified in Names Entered by SE database. Unable to find product characteristics in commonly used drug database.
32.	Pulzium***	54	Proposed Proprietary Name was reviewed in OSE# (b) (4). (b) (4)
33.	Scoparium	54	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
34.	Thallium	54	Product is a homeopathic substance
35.	Truxcillin	54	Name identified in RxNorm database. RedBook database indicated this product as discontinued on 5/11/1995.
36.	Doxycline	53	International brand name for Doxycycline.
37.	O-xylene	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
38.	Perhexiline	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
39.	Phos-Flur	53	Name identified in RxNorm database. RedBook database indicated that this branded product was discontinued on 3/01/2009. Although generic equivalents are available, the generics are marketed under other brands: Prevident, Dentagel…etc. and do not look or sound similar to the proposed name Phoxilium.
40.	Podophyllin	53	Product is a homeopathic substance.
41.	Thonzonium	53	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
42.	Cyclonium	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
43.	Fungilin	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
44.	Helium	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
45.	Palladium	52	Name identified in RxNorm database. RedBook database indicated that: 1. Palladium chloride was discontinued on 1/09/2012 2. Palladium metallicum is a homeopathic substance
46.	Pinaverium	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
47.	Phospholipids	52	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
48.	(b) (4) ***	52	Name identified in Names Entered by SE database. Unable to find product characteristics in commonly used drug database.
49.	Busodium	51	Name identified in RxNorm database. RedBook database indicated that this product was discontinued on 1/27/1997 with no generic equivalent available.
50.	Polarcrillin	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
51.	Fendiline	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
52.	Frisium	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
53.	Loxicom	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
54.	Moxalactam	51	Trade name 'Moxam' was identified in Drugs @FDA database as discontinued while the generic is not available in the market.
55.	Palfium	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
56.	(b) (4)***	51	Product approved under new proprietary name 'Ulesfia'.
57.	Polacrilin	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
58.	Thorium	51	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
59.	Amoxidin	50	International brand name for Amoxicillin
60.	Cephalexim	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
61.	(b) (4)		
62.		50	Product approved under new proprietary name 'Dexilant'.
63.	NPH Insulin	50	Name identified in Drugs @FDA database. This is a discontinued product.
64.	K + Potassium	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.

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No.	Name	POCA Score (%)	Failure preventions
65.	Meclodium	50	Name identified in Drugs @FDA database. This is a discontinued product.
66.	Oxolamine	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
67.	Oxy Clean	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
68.	Phosphate ion	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
69.	Polycillin-N	50	Name identified in Drugs @FDA database. This is a discontinued product.
70.	Primaxin IM	50	Name identified in RxNorm database. RedBook database indicated that this product was discontinued on 4/30/2011
71.	Proxigel	50	Name identified in RxNorm database. RedBook database indicated that this product was discontinued on 7/01/2001
72.	Proxigermanium	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
73.	Proxyphylline	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
74.	Pyritidum	50	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug database.
75.	Roxilox	50	Name identified in Drugs @FDA database. This is a discontinued product.
76.	Roxiprin	50	Name identified in Drugs @FDA database. This is a discontinued product.
77.	Stoxil	50	Name identified in Drugs @FDA database. This is a discontinued product.

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/s/

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06/30/2014

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