CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208054Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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

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

Date of This Review:	November 18, 2015
Application Type and Number:	NDA 208054
Product Name and Strength:	Axumin (Fluciclovine ^{18}F) Injection, 335-8200 MBq/mL (9 - 221 mCi/mL)
Total Product Strength:	(b) (4)
Product Type:	Single Ingredient
Rx or OTC:	Rx
Applicant/Sponsor Name:	Blue Earth Diagnostics
Panorama #:	2015-1594701
DMEPA Primary Reviewer:	Michelle Rutledge, PharmD
DMEPA Team Leader:	Yelena Maslov, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Axumin, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed name are outlined in the reference section and Appendix A respectively. The Applicant submitted an external name study, conducted by [redacted] ([redacted] for this product.

1.1 PRODUCT INFORMATION

The following product information is provided in the September 28, 2015 proprietary name submission.

- Intended Pronunciation: ax ue' min
- Active Ingredient: Fluciclovine ^{18}F
- Indication of Use: Radioactive diagnostic agent for positron emission tomography imaging of men with suspected prostate cancer recurrence
- Route of Administration: Intravenous
- Dosage Form: Injection
- Strength: 335-8200 MBq/mL (9 - 221 mCi/mL)
- Dose and Frequency: 370 MBq (10 mCi) administered as a [redacted] intravenous injection. The recommended maximum volume of injection of undiluted Axumin is 5 mL.
- How Supplied: 30 mL multidose vials containing approximately 26 mL of a clear, colorless solution at a strength of 335-8200 MBq/mL (9-221 mCi/mL) fluciclovine 18 F at calibration time and date.
- Storage: 20°C to 25°C (68°F to 77°F); [redacted] The product does not contain a preservative. Store Axumin within the original container or equivalent radiation shielding. [redacted]

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that the proposed name would not misbrand the proposed product. DMEPA and the Division of Medical Imaging Products (DMIP) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

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

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

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

2.2.3 FDA Name Simulation Studies

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

2.2.4 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 30, 2015 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

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

Table 1. POCA Search Results	**Number of Names**
Highly similar name pair: combined match percentage score ≥70%	6
Moderately similar name pair: combined match percentage score ≥50% to ≤ 69%	242
Low similarity name pair: combined match percentage score ≤49%	13

[1]USAN stem search conducted on November 4, 2015.

[2] POCA search conducted on October 21, 2015.

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

The proposed product, Axumin, will be available in strength of 335-8200 MBq/mL (9 - 221 mCi/mL). Since this is not a typical strength/ is an unusual strength/ not commonly marketed strength, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Axumin that were not identified in POCA, and found to have an overlap in strength with Axumin.

Table 1A. eDRLS Search Results	**POCA score**
ANTIMONIUM TARTARICUM	16
APIS MELLIFICA	24
ARNICA MONTANA	29
ARNICA MONTANA (WHOLE PLANT)	12
Arnicare Arnica	20
Avedana Pain-Relieving	13

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

Our analysis of the 261 names contained in Table 1 determined 261 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 Medical Imaging Products (DMIP) via e-mail on November 10, 2015. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DMIP on November 16, 2015, they stated no additional concerns with the proposed proprietary name, Axumin.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Janet Anderson, OSE project manager, at 301-796-0675.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your September 28, 2015 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

   USAN Stems List contains all the recognized USAN stems.

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

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

Drugs@FDA

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

RxNorm

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

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

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

Division of Medication Errors Prevention and Analysis proprietary name consultation requests

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

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

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

APPENDICES

Appendix A

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e. drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names **with** overlapping or similar strengths or doses.

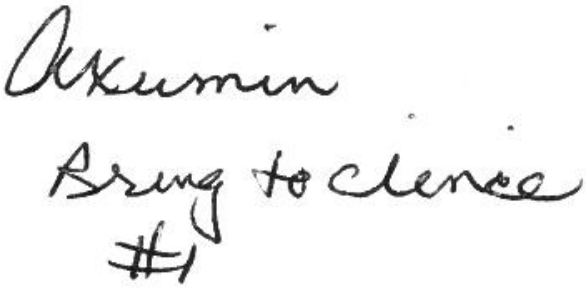
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Low Similarity Name Pair Checklist (i.e., combined score is ≤49%).

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Axumin Study (Conducted on October 23, 2015)

Handwritten Requisition Medication Order	Verbal Prescription
Medication Order: Axumin 10mCi (370 MBq) slow intravenous Outpatient Prescription: 	Axumin Bring to clinic #1

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

242 People Received Study
76 People Responded

Study Name: Axumin

Total	27	26	23	
INTERPRETATION	**OUTPATIENT**	**VOICE**	**INPATIENT**	**TOTAL**
ACZUMIN	0	1	0	1
AIXUMIN	0	0	1	1
AUXIMIN	0	0	1	1
AUXUMIN	2	0	0	2
AXIMIN	0	0	1	1
AXSUMAN	0	1	0	1
AXSUMIN	0	1	0	1
AXUMEN	0	10	0	10

AXUMIN	21	5	18	44
AXUMIN 10MCI (370MBQ)	0	0	1	1
AXURMIN	1	0	0	1
AXZUMEN	0	3	0	3
AXZUMIN	0	3	0	3
DEXUMIN	2	0	1	3
EXUMIN	0	1	0	1
EXZUMAN	0	1	0	1
OXUMIN	1	0	0	1

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

No.	**Proposed name:** Axumin **Established name:** Fluciclovine 18F **Dosage form:** Injection **Strength(s):** 335-8200 MBq/mL (9 - 221 mCi/mL) **Usual Dose:** 370 MBq (10 mCi) administered as a (b) (4) intravenous injection. The recommended maximum volume of injection of undiluted Axumin is 5mL.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
1.	AXUMIN***	100	Subject of this review
2.	ACTAMIN (Phonetic Score: 88)	78	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
3.	AKNEMIN (Orthographic Score: 73) (Phonetic Score: 77)	75	This name was identified by the RxNorm database. However, this product is an International product marketed in the UK.
4.	ECZEMIN (Phonetic Score: 85)	72	The prefixes in the names 'Axu' vs Ecz' appear different when scripted and offer some orthographic differences. In addition, these products have different settings of use.. Eczemin is a topical analgesic cream containing pramoxine, 1% which is available over-the-counter (OTC) vs Axumin is a radiopharmaceutical that can only be ordered and dispensed in radiological suit by a trained nuclear healthcare provider. Furthermore, Axumin is an injection for parenteral administration vs. Eczemin is a topical product. Both products differ in strength and dose. Based on the above reasons, in this instance, we believe the risk of confusion between these two names is reduced.

No.	**Proposed name:** Axumin **Established name:** Fluciclovine 18F **Dosage form:** Injection **Strength(s):** 335-8200 MBq/mL (9 - 221 mCi/mL) **Usual Dose:** 370 MBq (10 mCi) administered as a (b) (4) intravenous injection. The recommended maximum volume of injection of undiluted Axumin is 5mL.	**POCA Score (%)**	**Orthographic and/or phonetic differences in the names sufficient to prevent confusion** **Other prevention of failure mode expected to minimize the risk of confusion between these two names.**
5.	AXSAIN (Orthographic Score: 71)	70	The Axumin name contains an extra syllable. In addition, these products have different settings of use, which may help to decrease medications errors between these two products. Axsain is an OTC topical analgesic cream containing capsaicin 0.25%. vs Axumin is a radiopharmaceutical that can only be ordered and dispensed in radiological suit by a trained nuclear healthcare provider. Furthermore, Axumin is an injection for parenteral administration vs. Axsain is a topical product. Both products differ in strength and dose. Based on the above reasons, in this instance, we believe the risk of confusion between these two names is reduced.
6.	ALBUMIN (Orthographic Score: 80)	70	The infixes of this name pair have sufficient orthographic differences. The "-bu-" of Albumin contains an upstroke versus "-u-" of Axumin. In addition, these products have differences in dose and strength. Albumin is available in 5% or 25% strength and dosed 12.5g to 25 g; repeat as needed for hypovolemia versus Axumin which is available in 335-8200 MBq/mL (9 – 221 mCi/mL) and dosed 370 MBq (10 mCI), the maximum volume of injection of undiluted Axium is 5 mL as an diagnostic agent in prostate cancer.

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

No.	Name	POCA Score (%)
1.	ACTIMMUNE (Phonetic Score: 84)	66
2.	ELIXOMIN	66
3.	COSAMIN (Phonetic Score: 74)	64
4.	OPSUMIT (Phonetic Score: 75)	64
5.	ACTICIN (Phonetic Score: 70)	62
6.	AXIRON	62
7.	OSCIMIN	62
8.	RIFAXIMIN	62
9.	(b) (4) ***	61
10.	FLEXBUMIN	60
11.	YASMIN	60
12.	ANTIBEN	58
13.	KEDBUMIN	58
14.	PLASBUMIN	58
15.	PLASBUMIN-25	58
16.	PLASBUMIN-5	58
17.	XEOMIN	57
18.	AKNE-MYCIN	56
19.	ALUMINUM	56
20.	AQUA-BAN	56
21.	ARBUTIN	56
22.	ASENDIN	56
23.	AXID	56

No.	Name	POCA Score (%)
24.	AXITINIB (Note: This is the established name for Inlyta.)	56
25.	CURCUMIN	56
26.	TREMIN	56
27.	ACCUNEB	54
28.	AKTEN	54
29.	AK-TRACIN	54
30.	AMPHOCIN	54
31.	ATROPEN	54
32.	DIOSMIN	54
33.	EXELON	54
34.	HEMIN (Note: This is the established name for Panhematin.)	54
35.	MANGIMIN	54
36.	XIMINO	54
37.	ANU-MED	53
38.	ARTROSAMIN	53
39.	FRAGMIN	53
40.	HYDROXOMIN	53
41.	ADAPIN	52
42.	AK-CIDE	52
43.	AK-TAINE	52
44.	AMEN	52
45.	ASTELIN	52
46.	ATHROMBIN	52
47.	ATIVAN	52
48.	AXID AR	52

No.	Name	POCA Score (%)
49.	CYOMIN	52
50.	ALBUMINAR	51
51.	ALBUMINAR-25	51
52.	ALBUMINAR-5	51
53.	ANTITUSSIN	51
54.	APLENZIN	51
55.	APROTININ (Note: This is the established name of Traxylol.)	51
56.	ASPIRIN	51
57.	AVASTIN	51
58.	MECASERMIN (Note: This is the established name of Increlex.)	51
59.	ACTONEL	50
60.	AFRIN	50
61.	ALOEMINT	50
62.	ANCOBON	50
63.	ANTIMONY	50
64.	ANZEMET	50
65.	APIXABAN (Note: This is the established name for Eliquis.)	50
66.	AROMASIN	50
67.	LOTRIMIN	50
68.	METFORMIN	50
69.	RIDRAMIN	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:** Axumin **Established name:** Fluciclovine 18F **Dosage form:** Injection (Colorless) **Strength(s):** 335-8200 MBq/mL (9 - 221 mCi/mL) **Usual Dose:** 370 MBq (10 mCi) administered as a (b) (4) intravenous injection. The recommended maximum volume of injection of undiluted Axumin is 5mL.	**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.	AMMONIA N 13	50	The suffixes of this name pair have sufficient orthographic differences. The Ammonia N13 name contains extra syllables.
2.	AMMONIA N-13 (Note: This is an established name for Ammonia N 13.)	50	The suffixes of this name pair have sufficient orthographic differences. The Ammonia N13 name contains extra syllables.

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

No.	Name	POCA Score (%)
1.	AUGMENTIN	49
2.	HUMULIN	49
3.	ALFUZOSIN	49
4.	ALMOTRIPTAN	32
5.	AMOXICILLIN	42
6.	ATROVENT	42
7.	SINULIN	45

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.	OCUMIN (Phonetic Score: 74)	69	This name was identified by the (b) (4) database. However, this product is listed as deactivated in Redbook with no generic equivalents.
2.	A-G TUSSIN	66	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
3.	ACUPRIN 81	63	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find product characteristics in commonly used drug databases.
4.	ACTAMINE	61	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
5.	ACTACIN	60	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
6.	ATROMID (Phonetic Score: 70)	60	This name was identified by the Drugs at FDA and (b) (4) databases. The Brand is discontinued with no generic equivalent available. NDA 016099 withdrawn FR effective 6/16/2006.
7.	ACUPAN	59	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
8.	AMTUSSIN	59	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
9.	AFAXIN	58	This name was identified by the Drugs at FDA and (b) (4) databases. The Brand is discontinued with no generic equivalent available. ANDA 083187 withdrawn FR effective 11/19/1997.
10.	ALBUMINS	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
11.	AMOXIDIN	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
12.	APSIFEN	58	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
13.	PLASBUMIN-20	58	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
14.	ACTIN-N	57	This name was identified by the Drugs at FDA and (b) (4) databases. The Brand is discontinued with no generic equivalent available. NDA 017343 withdrawn FR effective 9/19/1996.
15.	ADVOCIN	57	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
16.	PLASMIN	57	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
17.	AKNEMYCIN	56	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
18.	ACLACIN	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
19.	ACTICON	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
20.	ASMAVEN	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
21.	EUCAMINT	55	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
22.	ACTAGEN	54	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find product characteristics in commonly used drug databases.
23.	ALEUDRIN	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
24.	ANTIMINTH	54	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
25.	ANXON	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
26.	ATOSIBAN	54	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
27.	AZAMUNE	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
28.	CYCLOMIN	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
29.	ERYMIN	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
30.	OVALBUMIN	54	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find complete product characteristics in commonly used drug databases.
31.	OXOLAMINE	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
32.	URIMIN	54	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
33.	ACTIBINE	53	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
34.	ANUMED	53	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find product characteristics in commonly used drug databases.
35.	AK-NEFRIN	52	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
36.	ALOXIPRIN	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
37.	APIGENIN	52	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
38.	ATROMID-S	52	This name was identified by the Drugs at FDA and (b) (4) databases. The Brand is discontinued with no generic equivalent available. NDA 016099 withdrawn FR effective 6/16/2006.
39.	AVOTERMIN	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
40.	AXOCET	52	This name was identified by the RxNorm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
41.	CONTIMIN	52	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
42.	OPTIMINE	52	This name was identified by the Drugs at FDA and (b) (4) databases. The Brand is discontinued with no generic equivalent available. NDA 017601 was withdrawn FR effective 4/4/2005.

No.	Name	POCA Score (%)	Failure preventions
43.	SURAMIN (Note: This is the established name for Metaret.)	52	This name was identified in the RxNorm database. However, we were unable to find complete product characteristics in commonly used drug databases.
44.	ACTINEX	51	This name was identified by the Drugs at FDA, RxNorm, and (b) (4) databases. The Brand is discontinued with no generic equivalent available.
45.	ALBUMINAR-20	51	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find product characteristics in commonly used drug databases.
46.	AMOXYMED	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
47.	A-PHEDRIN	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
48.	AQUACILLIN	51	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.

No.	Name	POCA Score (%)	Failure preventions
49.	ACCUTANE	50	This name was identified by the Drugs at FDA, Name Entered by Safety Evaluator, and Rx Norm databases. The Brand is discontinued with no generic equivalent available. NDA 018662 was withdrawn FR effective 11/22/2010.
50.	ACEMANNAN	50	This name was identified in the RxNorm and (b) (4) databases. However, we were unable to find complete product characteristics in commonly used drug databases.
51.	AKINETON	50	This name was identified by the Drugs at FDA, Rx Norm, and (b) (4) databases. The Brand is discontinued with no generic equivalent available.
52.	ALEXAN	50	This name was identified in the RxNorm database. However, is an international product marketed in various countries such as Australia, UK, and Mexico.
53.	ALEXAN	50	This name was identified in the RxNorm database. However, is an international product marketed in various countries such as Australia, UK, and Mexico.

No.	Name	POCA Score (%)	Failure preventions
54.	ANAMINE	50	This name was identified by the Rx Norm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.
55.	AQUASTAN	50	This name was identified in the RxNorm database. However, we were unable to find product characteristics in commonly used drug databases.
56.	ARAMINE	50	This name was identified by the Drugs at FDA, Rx Norm, and (b) (4) databases. The Brand is discontinued with no generic equivalent available. NDA 009509 was withdrawn FR effective 06/18/2009.
57.	FOLAMIN	50	This name was identified by the Rx Norm and (b) (4) databases. However, this product is listed as deactivated in Redbook with no generic equivalents.

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

No.	Name	POCA Score (%)
1.	EX-PAIN	66
2.	OXANID	64

No.	Name	POCA Score (%)
3.	EXEFEN	63
4.	EXAPRIN	62
5.	EXCEDRIN	62
6.	EXCEL 3 IN 1	62
7.	(b) (4) ***	62
8.	OXYMED	62
9.	DOXEPIN	61
10.	EXTINA	60
11.	EXIDINE	58
12.	EXOLAN	58
13.	FEXMID	58
14.	OXYFRIN	58
15.	OXYGEN	58
16.	PAXOFEN	58
17.	OCUMYCIN	57
18.	OCU-MYCIN	57
19.	DOXIDAN	56
20.	EQUIPIN	56
21.	LAXADAN	56
22.	MOCTANIN	56
23.	OXANDRIN	56
24.	OXILAN	55
25.	OXILAN-300	55
26.	OXILAN-350	55
27.	(b) (4) ***	54
28.	BIAXIN	54
29.	C TUSSIN	54
30.	ELOXATIN	54
31.	ESCULIN	54
32.	ESTIVIN	54

No.	Name	POCA Score (%)
33.	EXCENEL	54
34.	EXODERM	54
35.	MAXIPHEN	54
36.	NEXIUM IV	54
37.	OPTIMMUNE	54
38.	OXELADIN	54
39.	Q-TUSSIN	54
40.	SANTONIN	54
41.	SUMYCIN	54
42.	DEXACEN-4	53
43.	EULEXIN	53
44.	EVOXIN	53
45.	ZAXOPAM	53
46.	CYTAMEN	52
47.	(b) (4) ***	52
48.	DEXIUM	52
49.	DRAXXIN	52
50.	EDOXUDINE	52
51.	ENOXACIN	52
52.	EPANUTIN	52
53.	(b) (4) ***	52
54.	KAFOCIN	52
55.	MASTUSSIN	52
56.	MAXAQUIN	52
57.	MAXIBOLIN	52
58.	OCU-PHRIN	52
59.	OXIVENT	52
60.	OXYCONTIN	52
61.	OXYMETA-12	52
62.	OXYTOCIN	52

No.	Name	POCA Score (%)
63.	STAXYN	52
64.	TUSSCIDIN	52
65.	DYSMAN	51
66.	HEXALEN	51
67.	HUMATIN	51
68.	INSULIN	51
69.	MAXIMUM D3	51
70.	MAXIMUM-H	51
71.	MECLOMEN	51
72.	MOXILIN	51
73.	OTOCIDIN	51
74.	OXYBUTYNIN	51
75.	OXYNORM	51
76.	(b) (4) ***	51
77.	PAXIPAM	51
78.	SUMTAN	51
79.	TAB TUSSIN	51
80.	TRU-MICIN	51
81.	VUMON	51
82.	CALCIUM ION	50
83.	CO-TUSSIN	50
84.	DAKTARIN	50
85.	DEXACIDIN	50
86.	DEXONE	50
87.	DEXONE 0.5	50
88.	DEXONE 0.75	50
89.	DEXONE 1.5	50
90.	DEXONE 4	50
91.	ECPIRIN	50
92.	EDOXABAN	50

No.	Name	POCA Score (%)
93.	ENOXIMONE	50
94.	EXODUS	50
95.	(b) (4)***	50
96.	(b) (4)***	50
97.	EXUVIANCE	50
98.	FIDAXOMICIN	50
99.	FUCIDIN	50
100.	HEXADINE	50
101.	HEXAMIDINE	50
102.	HEXATUSSIN	50
103.	KG-TUSSIN	50
104.	MAXOLON	50
105.	MICAFUNGIN	50
106.	OCUFEN	50
107.	OPTOMYCIN	50
108.	ORFADIN	50
109.	PRAXBIND***	50
110.	Q-V TUSSIN	50
111.	RIXUBIS	50
112.	ROXIPRIN	50
113.	(b) (4)***	50
114.	ZOXIN	50

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

No.	Name	POCA Score (%)
1.	ANTIMONIUM TARTARICUM	16

No.	Name	POCA Score (%)
2.	APIS MELLIFICA	24
3.	ARNICA MONTANA	29
4.	ARNICA MONTANA (WHOLE PLANT)	12
5.	Arnicare Arnica	20
6.	Avedana Pain-Relieving	13

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/s/

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11/18/2015

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11/20/2015