CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212155Orig1s000

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:	Date
Application Type and Number:	NDA 212155
Product Name and Strength:	Cerianna (fluoroestradiol F-18) injection, 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Zionexa (Zionexa)
Panorama #:	2019-34672978
DMEPA Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

Contents

1 INTRODUCTION

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

1.1 REGULATORY HISTORY

Zionexa previously submitted the proposed proprietary name, (b) (4) *** on March 14, 2019. However, we found the name (b) (4) *** unacceptable, because it contained the United States Adopted Name (USAN) stem (b) (4), under NDA 212155 on June 7, 2019.[a]

Thus, Zionexa submitted the name, Cerianna, for review on September 24, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on September 24, 2019.

- Intended Pronunciation: Ser' ee' an' naa
- Active Ingredient: fluoroestradiol F-18
- Indication of Use: for use with positron emission tomography (PET imaging) for characterization of estrogen receptor (ER) status (b) (4) breast cancer
- Route of Administration: intravenous administration
- Dosage Form: injection
- Strength: 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL)
- Dose and Frequency: Recommended dose (b) (4) is 222 MBq with an allowable range from 111 to 222 MBq (3 – 6 mCi) (b) (4) using a suitably calibrated dose calibrator. The recommended maximum volume of injection of Fluoroestradiol F 18 Injection is 10 mL. (b) (4)
- How Supplied: 50 mL multiple-dose glass vial containing a solution of 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Fluoroestradiol F 18 at end of synthesis

[a] Vee, S. Proprietary Name Review for (b) (4) (NDA 212155). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 JUN 07. Panorama No. 2019-30004735.

- Storage: Store FLUOROESTRADIOL F 18 Injection at controlled room temperature (USP) 20°C to 25°C (68°F to 77°F). Store FLUOROESTRADIOL F 18 within the original container in radiation shielding.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Cerianna.

2.2.1 United States Adopted Names (USAN) Search

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

2.2.2 Components of the Proposed Proprietary Name

Zionexa indicated in their submission that the proposed proprietary name:

"The name Cerianna is an acronym composed of the following components. The first letter "C" indicates this is a diagnostic imaging agent represented by the full word "see" meaning "visualize". The "ER" is representative of the imaging target, the Estrogen Receptor. "Anna" is a commonly used female name which was selected to signify that breast cancer primarily occurs in females, and although breast cancer has been reported in males it is exceedingly rare hence the female name."

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 Comments from Other Review Disciplines at Initial Review

In response to the OSE, October 9, 2019 e-mail, the Division of Medical Imaging Products (DMIP) did not forward any comments or concerns relating to Cerianna at the initial phase of the review.

[b] USAN stem search conducted on October 2, 2019.

2.2.4 FDA Name Simulation Studies

Fifty-five (n=55) practitioners participated in DMEPA's prescription studies for Cerianna. 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.

2.2.5 Phonetic and Orthographic Computer Analysis (POCA) Search Results

Our POCA search[c] identified 293 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 1 below.

2.2.6 Names Retrieved for Review Organized by Name Pair Similarity

Table 1 lists the number of names retrieved from our POCA search. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 1. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	9
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	247
Low similarity name pair: combined match percentage score ≤54%	37

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

Our analysis of the 293 names contained in Table 1 determined none of the names will pose a risk for confusion with Cerianna 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 December 12, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Medical Imaging Products (DMIP) on December 17, 2019, they stated no additional concerns with the proposed proprietary name, Cerianna.

[c] POCA search conducted on October 2, 2019 in version 4.3.

3 CONCLUSION

The proposed proprietary name, Cerianna, is acceptable.

If you have any questions or need clarifications, please contact Tri Bui Nguyen, OSE project manager, at 240-402-3726.

3.1 COMMENTS TO ZIONEXA

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

If any of the proposed product characteristics as stated in your submission, received on September 24, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

1. *USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)*

   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 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. [d]

[d] 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 inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@fda, CernerRxNorm, and names in the review pipeline using a 55% threshold in POCA.

DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 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 are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in the confusion of drug names[e]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.
    - Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 4).

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

- 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 **≥55%** to **≤69%).**

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

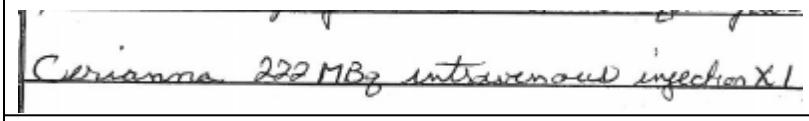
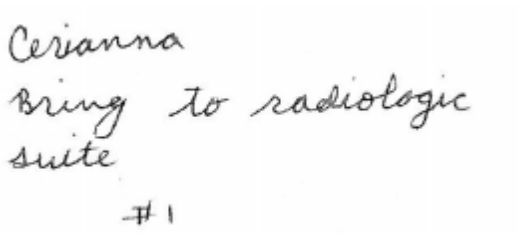
	Orthographic Checklist (Y/N to each question)	Phonetic Checklist (Y/N to each question)
	• Do the names begin with different first letters? Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* 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?	• 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 **≤54%).**

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

Appendix B: Prescription Simulation Samples and Results

Figure 1. Cerianna Study (Conducted on October 4, 2019)

Handwritten Medication Order/Prescription	Verbal Prescription
Medication Order:  Outpatient Prescription:  	Cerianna Bring to radiologic suite. Dispense #1

FDA Prescription Simulation Responses (Aggregate Report)

Study Name: Cerianna

215 People Received Study

55 People Responded

Total	19	18	18	55
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
CARIANNA	1	0	0	1
CERIANMA	0	0	1	1
CERIANNA	18	0	15	33
CERVIANNA	0	0	1	1
GERIANNA	0	0	1	1
SAREANA	0	1	0	1
SAREANNA	0	1	0	1
SAREONA	0	1	0	1
SARIANA	0	4	0	4
SARIONA	0	1	0	1
SEREANA	0	1	0	1
SERIANA	0	5	0	5
SERIANNA	0	2	0	2
SIREANNA	0	1	0	1
ZARIENA	0	1	0	1

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

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[f]	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.	Cerianna***	100	Subject of this review.
2.	Cerinta	83	Orthographic: The infixes/suffixes (anna vs. nta) provide some orthographic differences due to the upstroke letter 't'. Phonetic: Cerianna contains an extra syllable. The second (ee' vs. in) and third/fourth syllables (an' naa vs. ta) of this name pair have sufficient phonetic differences. Dose and frequency: Dose for Cerianna ranges from 111 MBq to 222 MBq (3 mCi to 6 mCi) once (b) (4) vs. the dose for Cerinta is 1 tablet daily or use as directed. There is no overlap in dose/frequency. Setting of Use: Cerinta is an oral contraceptive whereas Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical

[f] Recommended dose (b) (4) is 222 MBq with an allowable range from 111 to 222 MBq (3 – 6 mCi) (b) (4) using a suitably calibrated dose calibrator. The recommended maximum volume of injection of Fluoroestradiol F 18 Injection is 10mL. (b) (4)

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[f]	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.
			product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
3.	(b) (4) ***	81	(b) (4)

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[f]	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.
			(b) (4) [redacted] Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
4.	(b) (4) [redacted]***	80	Proposed proprietary name for ANDA 91209 found unacceptable by DMEPA (OSE# 2011-1224 and 2011-1225). ANDA 91209 approved without a proprietary name.
5.	Cerenia	80	Veterinary product.
6.	Ceresin	73	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
7.	Sericin 1	70	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[f]	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.
8.	Ceradon	70	Brand discontinued with no generic equivalents available. NDA 50601 withdrawn FR effective 07/25/1997.
9.	(b) (4)***	70	Proposed proprietary name for IND 115528 found unacceptable by DMEPA (OSE# 2019-30179475). Oriahnn*** submitted under NDA 213388 for this product.

Appendix D: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
10.	Cardene	60
11.	Jardiance	58
12.	(b) (4)***	58
13.	Riabni***	58
14.	Leribane	58
15.	(b) (4)***	57
16.	Soriatane	57
17.	Glycerin	56

Appendix E: Moderately Similar Names (e.g., combined POCA score is ≥55% to ≤69%) with overlap or numerical similarity in Strength and/or Dose

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
18.	Treanda	67	This name pair has sufficient orthographic and phonetic differences.
19.	Triam-A	66	This name pair has sufficient orthographic and phonetic differences.
20.	Serutan	66	This name pair has sufficient orthographic and phonetic differences.
21.	Ferrimin	66	This name pair has sufficient orthographic and phonetic differences.
22.	Ferrimin 150	66	This name pair has sufficient orthographic and phonetic differences.
23.	Sarene	64	Orthographic: Cerianna appears longer when scripted (8 letters vs. 6 letters). Phonetic: Cerianna contains two extra syllables. Dose and frequency: Dose for Cerianna ranges from 111 MBq to 222 MBq (3 mCi to 6 mCi) once (b) (4) vs. dose for Sarene is apply as needed. There is no direct overlap in dose or frequency. Setting of Use: Sarene is an OTC skin protectant whereas Cerianna will be

[g] Recommended dose (b) (4) is 222 MBq with an allowable range from 111 to 222 MBq (3 – 6 mCi) (b) (4) using a suitably calibrated dose calibrator. The recommended maximum volume of injection of Fluoroestradiol F 18 Injection is 10mL. (b) (4)

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
			prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
24.	Ceritinib	64	This name pair has sufficient orthographic and phonetic differences.
25.	Cyramza	63	This name pair has sufficient orthographic and phonetic differences.
26.	Qoliana	62	This name pair has sufficient orthographic and phonetic differences.
27.	Carimune	62	Phonetic: Cerianna contains an extra syllable. The first (Ser vs. Car) and third/fourth (an' naa vs. mune) syllables of this name pair have sufficient phonetic differences. Dose and frequency: Dose for Cerianna ranges from 111 MBq to 222 MBq (3 mCi to 6 mCi) once (b) (4) [redacted] vs. dose for Carimune is 0.4 g/kg to 0.8 g/kg once every 3 to 4 weeks or 0.4 g/kg on 2 to

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
			5 consecutive days. The doses are patient specific and there is no direct overlap in dose or frequency. Setting of Use: Carimune is a sterile, highly purified polyvalent antibody product containing in concentrated form all the IgG antibodies which regularly occur in the donor population and is indicated for the maintenance treatment of patients with primary immunodeficiencies (PID) (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, severe combined immunodeficiency) and Immune Thrombocytopenic Purpura. Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
28.	Trianex	62	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
29.	Triacin	61	This name pair has sufficient orthographic and phonetic differences.
30.	Periactin	61	This name pair has sufficient orthographic and phonetic differences.
31.	Cerefolin Nac	61	This name pair has sufficient orthographic and phonetic differences.
32.	Cerezyme	60	This name pair has sufficient orthographic and phonetic differences.
33.	Ceprotin	60	This name pair has sufficient orthographic and phonetic differences.
34.	Pacerone	60	This name pair has sufficient orthographic and phonetic differences.
35.	Cigensa***	60	This name pair has sufficient orthographic and phonetic differences.
36.	Cortane	60	This name pair has sufficient orthographic and phonetic differences.
37.	Talzenna	59	This name pair has sufficient orthographic and phonetic differences.
38.	Striant	59	This name pair has sufficient orthographic and phonetic differences.
39.	Cordran N	59	This name pair has sufficient orthographic and phonetic differences.
40.	Clarine	59	This name pair has sufficient orthographic and phonetic differences.
41.	Crinone	59	Phonetic: Cerianna contains two extra syllables. Strength: Cerianna is a single strength product whereas Crinone is available in 4% and 8%; the strength would need to be specified on a prescription/ medication order for Crinone.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
			Dose and Frequency: Dose for Cerianna ranges from 111 MBq to 222 MBq (3 mCi to 6 mCi) once (b) (4) vs. dose for Crinone is 1 applicator once daily, twice daily or every other day up to a total of six doses. There is no overlap in dose. Setting of Use: Crinone is a topical gel indicated for progesterone supplementation or replacement as part of an assisted reproductive technology treatment for infertile women with progesterone deficiency or treatment of secondary amenorrhea. Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
42.	(b) (4) ***	59	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
43.	Citroma	58	Orthographic: The upstroke letter 't' in Citroma provides some orthographic difference. Phonetic: First, second, and third syllables of this name pair have sufficient phonetic differences. Cerianna contains an extra syllable. Setting of Use: Citroma is an OTC saline laxative. Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
44.	Ceretec	58	This name pair has sufficient orthographic and phonetic differences.
45.	Cinryze	58	This name pair has sufficient orthographic and phonetic differences.
46.	Corisin	58	This name pair has sufficient orthographic and phonetic differences.
47.	(b) (4) ***	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
48.	Ceramide 3	58	This name pair has sufficient orthographic and phonetic differences.
49.	Cerubidin	58	This name pair has sufficient orthographic and phonetic differences.
50.	Ziana	58	This name pair has sufficient orthographic and phonetic differences.
51.	Cidacin	58	This name pair has sufficient orthographic and phonetic differences.
52.	Retin-A	58	This name pair has sufficient orthographic and phonetic differences.
53.	Triadine	57	This name pair has sufficient orthographic and phonetic differences.
54.	Acemannan	57	This name pair has sufficient orthographic and phonetic differences.
55.	Differin	56	This name pair has sufficient orthographic and phonetic differences.
56.	Cordran	56	This name pair has sufficient orthographic and phonetic differences.
57.	Cerefolin	56	This name pair has sufficient orthographic and phonetic differences.
58.	Claritin	56	This name pair has sufficient orthographic and phonetic differences.
59.	Chabelina***	56	This name pair has sufficient orthographic and phonetic differences.
60.	Cerliponase	56	This name pair has sufficient orthographic and phonetic differences.
61.	Clariscan***	56	This name pair has sufficient orthographic and phonetic differences.
62.	Uni-Cenna	56	This name pair has sufficient orthographic and phonetic differences.
63.	Brian Care	56	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
64.	Mericaine	56	This name pair has sufficient orthographic and phonetic differences.
65.	Lariam	55	This name pair has sufficient orthographic and phonetic differences.
66.	Priadel	55	This name pair has sufficient orthographic and phonetic differences.
67.	Cerovel	55	This name pair has sufficient orthographic and phonetic differences.
68.	Mepriam	55	This name pair has sufficient orthographic and phonetic differences.
69.	Cortenema	55	Orthographic: Upstroke letter 't' in Cortenema provides some orthographic difference. Phonetic: First, second, third, and fourth syllables of this name pair have sufficient phonetic differences. Dose and frequency: Dose for Cerianna ranges from 111 MBq to 222 MBq (3 mCi to 6 mCi) once (b) (4) [redacted] vs. dose for Cortenema is 1 enema once daily. There is no overlap in dose or frequency. Setting of Use: Cortenema is a hydrocortisone retention enema. Cerianna will be prepared by a nuclear pharmacy as the product is a radiopharmaceutical product for use

No.	Proposed name: Cerianna Established name: fluoroestradiol F-18 Dosage form: injection Strength(s): 148 MBq/mL to 3,700 MBq/mL (4 mCi/mL to 100 mCi/mL) Usual Dose: 222 MBq with an allowable range from 111 MBq to 222 MBq (3 mCi to 6 mCi)[g]	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
			with positron emission tomography (PET imaging) and is limited to specialized handling, preparation, and dispensing. The setting of use of these two products in the medication use process differ. Therefore, in this scenario, due to the above-mentioned factors and phonetic and orthographic differences, it is unlikely that these products would be confused for one another.
70.	Erwinaze	55 (O 72)	This name pair has sufficient orthographic and phonetic differences.

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

No.	Name	POCA Score (%)
71.	Anefrin	54
72.	(b) (4) ***	54
73.	Creatine	54
74.	Clenia	54
75.	R-Tanna	54
76.	R-Tanna 12	54
77.	Clearcanal	54
78.	Carnitine	53
79.	Caseinate	52
80.	Cinnamate	52
81.	Cerivastatin	52
82.	Cider Vinegar	52
83.	C-Tanna 12	52
84.	Rinatec	52
85.	Creatinine	52

No.	Name	POCA Score (%)
86.	Corticaine	51
87.	Dermacerin	51
88.	Eradacin	51
89.	Americaine	51
90.	Ceftriaxone	50
91.	Periciazine	50
92.	Crixivan	50
93.	Cariprazine	49
94.	Rinate	49
95.	Clearskin	48
96.	American Crew	48
97.	Caricia Care	48
98.	(b) (4)	48
99.	(b) (4)	48
100.	Articaine	48
101.	Cinqair	47
102.	Celadrin Cream	47
103.	Canineaid	47
104.	Cinnamedrine	46
105.	Rescinnamine	46
106.	Picea Mariana Resin	44
107.	Enhancer I	40

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
108.	Cerium	68	Product is not a drug. It is an element.
109.	Certiva	67	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
110.	Sarenin	66	Brand discontinued with no generic equivalents available. NDA 018009 withdrawn FR effective 09/29/1995.
111.	Sterane	66	Brand discontinued with no generic equivalents available. NDA 011446 withdrawn FR effective 05/12/1998. NDA 009996 withdrawn FR effective 09/17/2001.
112.	Serine	66	Product is not a drug. It is a non-essential amino acid.
113.	Ceron	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

No.	Name	POCA Score (%)	Failure preventions
114.	Icarii	66	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
115.	Cereflin	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
116.	Raciran	64	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
117.	Prefrin-A	64	Brand discontinued with no generic equivalents available. NDA 007953 withdrawn FR effective 01/21/1974.
118.	Ceraxon	64	International product marketed in Ukraine.
119.	Cycrin	63	Brand discontinued with no generic equivalents available. ANDA 081239, 081240, 089386 withdrawn FR effective 04/28/2003.
120.	(b) (4) ***	62	Name identified in Names Entered by Safety Evaluator database. Unable to find product characteristics in internal databases.
121.	Chardonna	62	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
122.	Circanol	62	Brand discontinued with no generic equivalents available. ANDA 084868 and 085809 withdrawn FR effective 02/22/1991.
123.	Kera Nail	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
124.	Tacrine	62	Brand discontinued with no generic equivalents available. NDA 020070 withdrawn FR effective 08/19/2013.
125.	Rice Bran	62	Product is not a drug. It is a cleansing foam.
126.	Triotann	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
127.	Revina	60	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
128.	Centrine	60	Veterinary product.
129.	Geranial	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
130.	Caprin	60	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
131.	Toceranib	60	Veterinary product.
132.	Serenus	58	Veterinary product.

No.	Name	POCA Score (%)	Failure preventions
133.	Solian	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
134.	Carisoma	58	International product marketed in United Kingdom.
135.	Ceramide 1	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
136.	Ceramide 2	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
137.	Jeridin	58	International product formerly marketed in United Kingdom.
138.	Tri-Tannate	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
139.	Enterocina	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
140.	Keracyanin	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
141.	Carrageenan	58	Product is not a drug. It is a raw material for compounding.
142.	(b) (4) ***	57	(b) (4)
143.	Corwin	57	International product formerly marketed in United Kingdom and Belgium.
144.	Ceron-Dm	57	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
145.	Micrainin	57	Brand discontinued with no generic equivalents available. ANDA 084978 withdrawn FR effective 11/12/2015.
146.	Citrate	56	Product is not a drug. It is derivative of citric acid not available as a stand alone product.
147.	Gerimal	56	Brand discontinued with no generic equivalents available. ANDA 086188, 086189, 088207 withdrawn FR effective 02/01/2018, 11/24/2017, and 06/06/1990, respectively.
148.	Ceramides	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
149.	Ceredase	56	Brand discontinued with no generic equivalents available. NDA 020057 withdrawn FR effective 04/18/2012.

No.	Name	POCA Score (%)	Failure preventions
150.	Carvone	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
151.	Pyril Tann-12	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
152.	Meridia	56	Brand discontinued with no generic equivalents available. NDA 020632 withdrawn FR effective 12/21/2010.
153.	Cedilanid-D	56	Brand discontinued with no generic equivalents available. NDA 009282 withdrawn FR effective 11/05/1992.
154.	Cerumenex	56	Brand discontinued with no generic equivalents available. NDA 011340 withdrawn FR effective 06/16/2006.
155.	Cephradine	56	Brand discontinued with no generic equivalents available. ANDA 062683, 062762, 062813, 062850, 062851, 062858, 062859 withdrawn FR effective 11/03/2016, 09/09/1997, 11/12/1991, 01/05/2015, 01/05/2015, 01/05/2015, 01/05/2015, respectively.
156.	Tricaine	56	Veterinary product.
157.	Carminate	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
158.	Cinnarizine	56	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
159.	Triam	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
160.	Barbidonna	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
161.	Chlor-Tan A 12	55	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
162.	(b) (4) ***	55	(b) (4)
163.	Erwinase	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
164.	Cafedrine	55	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.

Appendix H: Names not likely to be confused due to absence of attributes that are known to cause name confusion[h].

No.	Name	POCA Score (%)
165.	Teronac	67
166.	Verelan	66
167.	Zeranol	64
168.	Serenace	64
169.	Sarna	62
170.	Forane	62
171.	Sarapin	62
172.	Torecan	62
173.	Ser-A-Gen	62
174.	Varithena	62
175.	Terocin	62
176.	Mirena	62
177.	Fetrin	61
178.	Triban	61
179.	Zetran	61
180.	Xerava	60
181.	Kirwan	60
182.	Fiorinal	60
183.	Sandrena	60
184.	Furacin	60
185.	(b) (4) ***	60
186.	Secretin	60
187.	Dermasana	60
188.	Pileran	60
189.	(b) (4) ***	60
190.	Peroxin A	60
191.	Peroxin A 10	60
192.	Serpalan	59
193.	Daricon	59
194.	Sparine	59
195.	Migran-A	59
196.	Xerac Ac	59

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

No.	Name	POCA Score (%)
197.	Termene	58
198.	Ferratab	58
199.	Suramin	58
200.	Suprane	58
201.	Survanta	58
202.	Viranol	58
203.	Sorine	58
204.	Erleada	58
205.	Kerydin	58
206.	Treagan	58
207.	Zirgan	58
208.	Spirulina	58
209.	Salicin	58
210.	Septrin	58
211.	Roferon-A	58
212.	A-Phedrin	58
213.	Heroin	58
214.	Larin 24 Fe	58
215.	Larin Fe 1.5/30	58
216.	Larin Fe 1/20	58
217.	Servira	58
218.	Teramine Er	58
219.	Ethrane	58
220.	Zephiran	58
221.	Serpanray	58
222.	Theracran	58
223.	Peranex	58
224.	Teramine	58
225.	Etrafon-A	58
226.	Etrafon-A	58
227.	Tridrane	58
228.	Verazinc	58
229.	Tridane	58
230.	Terfinax	58
231.	Nesina	58
232.	Serzone	57
233.	Furalan	57
234.	Vaprino	57
235.	1,4-Sorbitan	57
236.	Sorbitan	57

No.	Name	POCA Score (%)
237.	Viramune	57
238.	Trinessa	57
239.	(b) (4) ***	57
240.	Acitretin	57
241.	Dermacin	57
242.	Excedrin	57
243.	Viread	56
244.	Surolan	56
245.	Ferocon	56
246.	(b) (4) ***	56
247.	Xuriden	56
248.	Ferate	56
249.	Phor Pain	56
250.	Firvanq	56
251.	(b) (4) ***	56
252.	Paradyne	56
253.	Sarolaner	56
254.	Aspirin	56
255.	Brovana	56
256.	Femring	56
257.	Ferronate	56
258.	Perestan	56
259.	Miranel	56
260.	Taurine	56
261.	Felbinac	56
262.	Tetracyn	56
263.	Trionate	56
264.	(b) (4) ***	56
265.	Vectrin	56
266.	Tetracon	56
267.	Berman	56
268.	Irenka	56
269.	Pentran	56
270.	Zactran	56
271.	Ecpirin	56
272.	Perazine	56
273.	Edecrin	56
274.	Heparin	56
275.	Nevanac	56
276.	Aricin	56

No.	Name	POCA Score (%)
277.	Ferric Cation	56
278.	R A Acne	56
279.	Errin	56
280.	Falmina	55
281.	Fybranta	55
282.	Paraffin	55
283.	Vetripen	55
284.	Diprivan	55
285.	Freamine 6.9	55
286.	Freamine 8.5%	55
287.	Pepsin A	55
288.	(b) (4) ***	55
289.	Larin 1.5/30	55
290.	Larin 1/20	55
291.	Percodan	55
292.	Anergan	55
293.	Anergan 50	55

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PROPRIETARY NAME REVIEW
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Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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Date of This Review:	June 7, 2019
Application Type and Number:	NDA 212155
Product Name and Strength:	(b) (4) (Fluoroestradiol F-18) injection, 148 mBq/mL – 3,700 MBq/mL (4 mCi/mL – 100 mCi/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Zionexa US Corp (Zionexa)
Panorama #:	2019-30004735
DMEPA Safety Evaluator:	Sarah K. Vee, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD
DMEPA Assoc. Director:	Mishale Mistry, PharmD, MPH

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