

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

207533Orig1s000

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 12, 2014
Application Type and Number:	NDA 207533
Product Name and Strength:	Aristada (Aripiprazole Lauroxil) Extended-release Injectable Suspension 441 mg, 662 mg, and 882 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Alkermes, Inc.
Submission Date:	August 22, 2014
Panorama #:	2014-26199
DMEPA Primary Reviewer:	Loretta Holmes, BSN, PharmD
DMEPA Associate Director:	Irene Z. Chan, PharmD, BCPS

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Aristada, 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] ^{(b) (4)} for this product.

1.1 REGULATORY HISTORY

The Division of Medication Error Prevention and Analysis (DMEPA) previously reviewed the name Aristada under IND 107249 and found the name acceptable.¹ The name was resubmitted for our review on August 22, 2014 under NDA 207533.

1.2 PRODUCT INFORMATION

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

- Intended Pronunciation: air-is-TAH-dah
- Active Ingredient: Aripiprazole Lauroxil
- Indication of Use: Treatment of Schizophrenia
- Route of Administration: Administer Aristada either in the deltoid muscle (441 mg dose only) or gluteal muscle (441 mg, 662 mg or 882 mg).
- Dosage Form: Extended-release Injectable Suspension
- Strengths: 441 mg, 662 mg, and 882 mg
- Dose and Frequency: 441 mg, 662 mg, or 882 mg intramuscularly once monthly or 882 mg every 6 weeks
- How Supplied: Kits containing the following:
 - The 441 mg strength kit contains three safety needles; a 1-inch 21 gauge, a 1½-inch 20-gauge, and a 2-inch 20 gauge needle.
 - The 662 mg strength kit contains two safety needles; a 1½-inch 20 gauge, and a 2-inch 20 gauge needle.
 - The 882 mg strength kit contains two safety needles; a 1½-inch 20 gauge, and a 2-inch 20 gauge needle.
- Storage: Store at room temperature 20°C to 25°C (68°F to 77°F) with brief excursions permitted between 15°C and 30°C (between 59°F and 86°F).

¹ Holmes L. Proprietary Name Review for Aristada (IND 107249). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2013 Jul 01. 38 p. OSE RCM No.: 2013-147.

2 RESULTS

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

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

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

2.2.1 *United States Adopted Names (USAN) Search*

There is no USAN stem present in the proprietary name².

2.2.2 *Components of the Proposed Proprietary Name*

The Applicant indicated in their submission that the proposed name, Aristada, is coined from aripiprazole. 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*

One hundred 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. Eighteen participants in the verbal study misinterpreted the letter "d" as the letter "t" and eight participants in the same study misinterpreted the beginning letter "A" as the letter "E". Ten participants in the inpatient written study misinterpreted the beginning letter "A" as the letter "S". 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, September 9, 2014 e-mail, the Division of Psychiatry Products (DPP) did not forward any comments or concerns relating to the proposed proprietary name at the initial phase of the review.

2.2.5 *Phonetic and Orthographic Computer Analysis (POCA) Search Results*

Table 1 lists the number of names with the combined orthographic and phonetic score of $\geq 50\%$ retrieved from our POCA search³ organized as highly similar, moderately similar or low similarity for further evaluation. Table 1 also includes names identified by (b) (4) and the primary safety evaluator.

²USAN stem search conducted on September 23, 2014.

³ POCA search conducted on September 23, 2014.

Table 1. POCA Search Results	Number of Names
Highly similar name pair: combined match percentage score $\geq 70\%$	8
Moderately similar name pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$	235
Low similarity name pair: combined match percentage score $\leq 49\%$	6

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

Our analysis of the 249 names contained in Table 1 determined that none of the 249 names will pose a risk for confusion as described in Appendices C through H.

2.2.7 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on October 27, 2014. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from DPP on November 5, 2014, they stated no additional concerns with the proposed proprietary name, Aristada.

3 CONCLUSIONS

The proposed proprietary name is acceptable. If you have further questions or need clarifications, please contact Vasantha Ayalasomayajula, OSE Project Manager, at 240-402-5035.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 22, 2014 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

4 REFERENCES

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

USAN Stems List contains all the recognized USAN stems.

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

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

3. **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).

4. **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#>).

5. **Division of Medication Errors Prevention and Analysis proprietary name consultation requests**

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

APPENDICES

Appendix A

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

1. **Misbranding Assessment:** For prescription drug products, OPDP assesses the name for misbranding concerns. . For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by DNCE. OPDP or DNCE evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or DNCE provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.
2. **Safety Assessment:** The safety assessment is conducted by DMEPA, and includes the following:
 - a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 2*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.⁴

⁴ 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 $\geq 70\%$.
 - Moderately similar pair: combined match percentage score $\geq 50\%$ to $\leq 69\%$.
 - Low similarity: combined match percentage score $\leq 49\%$.

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 $\geq 70\%$).

<u>Orthographic Checklist</u>		<u>Phonetic Checklist</u>	
Y/N	Do the names begin with different first letters? <i>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</i>	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? <i>*FDA considers the length of names different if the names differ by two or more letters.</i>	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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 as 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 $\geq 50\%$ to $\leq 69\%$).

<p>Step 1</p>	<p>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.</p> <p>For single strength products, also consider circumstances where the strength may not be expressed.</p> <p>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.</p> <p>To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion:</p> <ul style="list-style-type: none"> ○ 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
<p>Step 2</p>	<p>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.</p>

<p>Orthographic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names begin with different first letters? <p>Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.</p> <ul style="list-style-type: none"> • Are the lengths of the names dissimilar* when scripted? <p>*FDA considers the length of names different if the names differ by two or more letters.</p> <ul style="list-style-type: none"> • Considering variations in scripting of some letters (such as <i>z</i> and <i>f</i>), 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? 	<p>Phonetic Checklist (Y/N to each question)</p> <ul style="list-style-type: none"> • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?
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Table 5: Low Similarity Name Pair Checklist (i.e., combined score is $\leq 49\%$).

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. Aristada Study (Conducted on September 5, 2014)

Handwritten Requisition Medication Order	Verbal Prescription
<u>Medication Order:</u> <i>Aristada 882 mg IM once monthly</i>	Aristada 662 mg Bring to clinic Dispense #1
<u>Outpatient Prescription:</u> <i>Aristada 662 mg Bring to clinic #1</i>	

FDA Prescription Simulation Responses (Aggregate 1 Rx Studies Report)

260 People Received Study				
100 People Responded				
Study Name: Aristada				
Total	31	31	38	
INTERPRETATION	OUTPATIENT	VOICE	INPATIENT	TOTAL
AERASTADA	0	2	0	2
AEROSTADA	0	2	0	2
ARASTADA	0	1	0	1
ARASTATA	0	1	0	1
ARASTOTTA	0	1	0	1
ARESTADA	0	1	0	1
ARISTADA	31	4	26	61
ARISTADAD	0	0	1	1
ARISTATA	0	8	0	8
ARISTATDA	0	0	1	1
ARISTOTA	0	2	0	2
ARRESTATA	0	1	0	1
ERISTADA	0	2	0	2
ERISTATA	0	3	0	3
ERISTOTA	0	1	0	1
ERRASTADA	0	1	0	1
ERRASTATA	0	1	0	1
SRISTADA	0	0	8	8
STRISTADA	0	0	2	2

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

No.	<u>Proposed name:</u> Aristada (Aripiprazole Lauroxil) <u>Strength(s):</u> 441 mg, 662 mg, and 882 mg <u>Usual Dose:</u> 441 mg, 662 mg, or 882 mg intramuscularly once monthly or 882 mg every 6 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
1.	Arista AH	75	The root name “Arista” was identified by DMEPA and the (b) (4) external study as a name with look-alike and sound-alike similarities to Aristada. However, the suffixes of this name pair have sufficient orthographic differences. Additionally, Aristada contains an extra syllable. Furthermore, Arista AH (a plant based absorbable surgical hemostatic powder) is a device indicated for use in surgical procedures as an adjunctive hemostatic device; thus its setting of use makes it unlikely to be confused with Aristada.
2.	aristopak	72	The suffixes of this name pair have sufficient orthographic differences. The fourth syllables of this name pair sound different. Additionally, the products do not overlap in strength or dose.
3.	(b) (4)***	72	The prefixes and suffixes of this name pair have sufficient orthographic differences The first/second/third syllables of this name pair sound different. Aristada contains an extra syllable.
4.	Orastat	71	The suffixes of this name pair have sufficient orthographic differences. Aristada contains an extra syllable. Additionally, the products do not overlap in strength or dose.
5.	ARESTIN	70	The suffixes of this name pair have sufficient orthographic differences The third syllables of this name pair sound different. Aristada contains an extra syllable.

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No.	Proposed name: Aristada (Aripiprazole Lauroxil) Strength(s): 441 mg, 662 mg, and 882 mg Usual Dose: 441 mg, 662 mg, or 882 mg intramuscularly once monthly or 882 mg every 6 weeks	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion
6.	Tavist DA	70	The prefixes and suffixes of this name pair have sufficient orthographic differences The first and second syllables of this name pair sound different. Aristada contains two extra syllables.
7.	Uristat	70	The suffixes of this name pair have sufficient orthographic differences. Aristada contains an extra syllable. Additionally, the products do not overlap in strength or dose.

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

No.	Proposed Name	POCA Score (%)
1.	ariXTRA	68
2.	(b) (4) ***	68
3.	LYSTEDA	67
4.	Dristan	66
5.	aristOSPAN	65
6.	(b) (4) ***	65
7.	aristOGEL	64
8.	Perestan	64
9.	aristOCORT A	63
10.	ERGOstaT	63
11.	(b) (4) ***	62

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No.	Proposed Name	POCA Score (%)
12.	FARESTON	62
13.	Verrustat	62
14.	Aerospan	60
15.	CARBAstaT	60
16.	EVista	60
17.	Histadec	60
18.	Histatab	60
19.	Histatan	60
20.	STERI-staT	60
21.	UrisPAS	60
22.	Alustra	59
23.	Carlesta	59
24.	ELEstaT	59
25.	REstaSIS	59
26.	RiastaP	59
27.	Allres Pd	58
28.	ALPROstadIL	58
29.	ariCEPT	58
30.	Derma stat	58
31.	istODAX	58
32.	Klerist-D	58
33.	OXistaT	58
34.	PERIOstaT	58
35.	risaQuad	58
36.	risPERDAL	58
37.	Therastat	58
38.	Tri-statin	58
39.	Vagistat	58
40.	VAGistaT-1	58
41.	Arcapta	57

No.	Proposed Name	POCA Score (%)
42.	ariCEPT ODT	57
43.	AEROSPAN HFA	56
44.	Alahist AC	56
45.	Ala-Hist AC	56
46.	AREDIA	56
47.	aristOCORT	56
48.	Cortastat LA	56
49.	Histade	56
50.	Irospan	56
51.	Respi-TANN	56
52.	Restall	56
53.	Tavist-D	56
54.	TRIOstaT	56
55.	Urised	56
56.	VariTHENA	56
57.	VistIDE	56
58.	Ala-Hist D	55
59.	HIBistaT	55
60.	Rosadan	55
61.	Amerituss AD	54
62.	CYstadaNE	54
63.	DIAstaT	54
64.	Hydrostat	54
65.	stahist AD	54
66.	Allerest PE	53
67.	AMITIZA	53
68.	ANEstaCON	53
69.	Cortastat	53
70.	Cortastat 10	53
71.	Histatab D	53

No.	Proposed Name	POCA Score (%)
72.	Hista-Tabs	53
73.	PREZista	53
74.	PristIQ	53
75.	Allerhist-D	52
76.	Anaspaz	52
77.	Anestafoam	52
78.	Antispas	52
79.	ARAVA	52
80.	Argesic-SA	52
81.	aridex-D	52
82.	(b) (4)***	52
83.	ATRIPLA	52
84.	(b) (4)***	52
85.	Cal stat	52
86.	Durahist D	52
87.	FORTEsta	52
88.	KOROstaTIN	52
89.	NITROstaT	52
90.	Sinustab	52
91.	(b) (4)***	52
92.	TRUVada	52
93.	Vistacot	52
94.	Altatapp	51
95.	Atrac-Tain	51
96.	Dristan Cold	51
97.	Histatab PH	51
98.	MONistaT 3	51
99.	MONistaT 7	51

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No.	Proposed Name	POCA Score (%)
100.	Monistat-1	51
101.	Replesta	51
102.	Ru Hist D	51
103.	Trelstar LA	51
104.	Tuzistra ***	51
105.	Aler-Tab	50
106.	Allres DS	50
107.	ambrisentan	50
108.	AMITID	50
109.	Antara	50
110.	apixaban	50
111.	Aralast	50
112.	(b) (4) ***	50
113.	aricin	50
114.	aridex	50
115.	ariMIDEX	50
116.	Articadent	50
117.	Ascriptin	50
118.	Aspirtab	50
119.	Auryxia***	50
120.	Bacti-stat	50
121.	BrisDELLE	50
122.	Dayhist-D	50
123.	HistaFED	50
124.	Histafed LA	50
125.	LAstaCAFT	50
126.	Lemtrada ***	50
127.	Pilostat	50

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No.	Proposed Name	POCA Score (%)
128.	(b) (4)***	50
129.	Threostat	50
130.	<p data-bbox="331 457 873 674">Strattera was identified in the (b) (4) external study. Although the POCA score is less than 50% we evaluated the name further because names beginning with the letter “S” were identified in our Rx study results.</p> <p data-bbox="331 695 873 877">The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences. The first/second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p> <p data-bbox="331 898 873 961">Strattera does not overlap in strength or dose with Aristada.</p>	

Appendix E: Moderately Similar Names (e.g., combined POCA score is $\geq 50\%$ to $\leq 69\%$) with overlap or numerical similarity in Strength and/or Dose

No.	<u>Proposed name:</u> Aristada (Aripiprazole Lauroxil) <u>Strength(s):</u> 441 mg, 662 mg, and 882 mg <u>Usual Dose:</u> 441 mg, 662 mg, or 882 mg intramuscularly once monthly or 882 mg every 6 weeks	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.	AGGRAsTaT	58	<p>The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The second syllables of this name pair sound different. Aristada contains an extra syllable.</p>
2.	AVASTIN	54	<p>The infixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p>
3.	BristaGEN	54	<p>The prefixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The first/second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p>
4.	Capastat	54	<p>The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The first/second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p>
5.	Respigam	54	<p>The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The first/second/third syllables of this name pair sound different. Aristada name contains an extra syllable.</p>
6.	AZACTAM	52	<p>The prefixes/infixes/suffixes of this name pair have sufficient orthographic differences</p> <p>The second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p>

No.	Proposed name: Aristada (Aripiprazole Lauroxil) Strength(s): 441 mg, 662 mg, and 882 mg Usual Dose: 441 mg, 662 mg, or 882 mg intramuscularly once monthly or 882 mg every 6 weeks	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
7.	ancestim	50	<p>The suffixes of this name pair have sufficient orthographic differences</p> <p>The first/second/third syllables of this name pair sound different. Aristada contains an extra syllable.</p>

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

No.	Name	POCA Score (%)
1.	Artane	45
2.	Estradiol	45
3.	Aripiprazole	43
4.	Adacel	36
5.	Granisetron	34

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.	aristada	100	This name is the subject of this review.
2.	Orostat	68	This name could not be found in our usual drug information databases.
3.	Respa-SA	68	This name could not be found in our usual drug information databases.
4.	Agistam	66	This name could not be found in our usual drug information databases.
5.	Arpida	64	This is the name of a pharmaceutical company.
6.	(b) (4)***	64	This was an alternate name that was not reviewed by DMEPA. The primary name was found acceptable.
7.	Carisoma	60	This name could not be found in our usual drug information databases.
8.	Restandol	58	This name could not be found in our usual drug information databases.
9.	rispas	58	This name could not be found in our usual drug information databases.
10.	ARFONAD	56	Dosing information could not be found in our usual drug information databases.
11.	(b) (4)***	56	This name was withdrawn by the applicant and was not reviewed by DMEPA.
12.	BARstaTIN 100	56	Dosing information could not be found in our usual drug information databases.
13.	Myristate	56	This name could not be found in our usual drug information databases.
14.	(b) (4)***	56	This name was withdrawn by the applicant and was not reviewed by DMEPA.
15.	Crystal B-12	55	This name could not be found in our usual drug information databases.
16.	Aquastan	54	Product characteristics could not be found in our usual drug information databases.

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No.	Name	POCA Score (%)	Failure preventions
17.	arisoprodol	54	This name could not be found in our usual drug information databases.
18.	Astagraf	54	This name could not be found in our usual drug information databases.
19.	tolrestat	54	This name could not be found in our usual drug information databases.
20.	Prostap 3	53	This name could not be found in our usual drug information databases.
21.	aniracetam	52	This name could not be found in our usual drug information databases.
22.	Antisedan	52	This is a veterinary product.
23.	Crystapen	52	This name could not be found in our usual drug information databases.
24.	Cyprostat	52	This name could not be found in our usual drug information databases.
25.	Eradacin	52	This name could not be found in our usual drug information databases.
26.	(b) (4) ***	52	This was an alternate name that was not reviewed by DMEPA. The primary name was found acceptable.
27.	Opustan	52	This name could not be found in our usual drug information databases.
28.	Trisofed	52	This name could not be found in our usual drug information databases.
29.	Vistacon	52	This name could not be found in our usual drug information databases.
30.	Vistra	52	This name could not be found in our usual drug information databases.
31.	aristocort R	51	The root name "Aristocort" with the modifier "R" could not be found in our usual drug information databases. The root name "Aristocort" is evaluated in Table D.
32.	Histine D	51	This name could not be found in our usual drug information databases.

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No.	Name	POCA Score (%)	Failure preventions
33.	MONistaT	51	This is a family tradename. A modifier would be required in order to determine the product to be dispensed. There are no strength or dose overlaps between the Monistat product line products identified and Aristada.
34.	MONistaT 5	51	This root name with the modifier “5” could not be found in our usual drug information databases.
35.	AZINTAMIDE	50	This name could not be found in our usual drug information databases.
36.	Crystacide	50	This name could not be found in our usual drug information databases.
37.	Ed A-Hist LA	50	This name could not be found in our usual drug information databases.
38.	Laxadan	50	This name could not be found in our usual drug information databases.
39.	Vitadil 2A	50	This name could not be found in our usual drug information databases.
40.	Vitadil 5A	50	This name could not be found in our usual drug information databases.

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

No.	Name	POCA Score (%)
1.	Respa DM	61
2.	EGRIFTA	59
3.	(b) (4)***	59
4.	Visqid AA	58
5.	Erythroped A	57
6.	Duratuss DA	56
7.	RAPTIVA	56
8.	TARACTAN	56

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No.	Name	POCA Score (%)
9.	ERY-TAB	55
10.	Oragest TD	55
11.	RESCULA	55
12.	(b) (4)***	54
13.	OralTag***	54
14.	Respa C&C	54
15.	respimat***	54
16.	Restone	54
17.	RibaTab	54
18.	RIFADIN	54
19.	LAROTID	53
20.	Respa AR	53
21.	Respa-A.R.	53
22.	Respa-BR	53
23.	Respbid	53
24.	Ritifed	53
25.	COLESTID	52
26.	Dermasana	52
27.	Elantan LA	52
28.	ESTRATAB	52
29.	FARXIGA	52
30.	Respa	52
31.	Respa-1st	52
32.	Respa-GF	52
33.	RETIN-A	52
34.	SEROSTIM	52
35.	SUSTIVA	52
36.	Tripedia	52

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No.	Name	POCA Score (%)
37.	DARVOCET A500	51
38.	Estra-D	51
39.	EXTAVIA	51
40.	(b) (4)***	51
41.	ORFADIN	51
42.	(b) (4)***	51
43.	Uric Acid	51
44.	Dispas	50
45.	Duratuss A	50
46.	Ellis Tonic	50
47.	ERAXIS	50
48.	ERIVEDGE	50
49.	ERYCETTE	50
50.	Estro-Span	50
51.	Estro-Span 40	50
52.	Jevtana***	50
53.	ORACEA	50
54.	(b) (4)***	50
55.	Respa-A.R.M.	50
56.	Respa-PE	50
57.	Resperal	50
58.	(b) (4)***	50
59.	Tresiba***	50
60.	VICTOZA	50

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/s/

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11/12/2014

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11/12/2014