CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209830Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME MEMORANDUM

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

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

Date of This Review:	May 26, 2018
Application Type and Number:	NDA 209830
Product Name and Strength:	Aristada Initio (aripiprazole lauroxil) extended release injectable suspension 281.3 mg/mL
Total Product Strength:	675 mg/2.4 mL
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Alkermes, Inc.
Panorama #:	2018-21453733
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Aristada Initio, based on the revised strength (b) (4) 675 mg/2.4 mL. The proposed proprietary name, Aristada Initio, was found acceptable under NDA 209830 on November 29, 2017.[a]

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 Comments from Other Review Disciplines at Initial Review

In response to the OSE, March 14, 2018 email, the Division of Psychiatry Products (DPP) expressed concern that due to the similarity of the names, the products Aristada and Aristada Initio could be confused. DPP suggested reversing the order of the name (i.e., Initio Aristada) to better differentiate the names. However, we reiterated our position that the name is acceptable from a medication error perspective given the totality of information considered in our previous proprietary name review.[b] We offered to schedule a teleconference between DPP and the Applicant so that the Division could discuss their concerns with the Applicant and suggest alternate names. DPP declined and stated they defer to DMEPA on the acceptability of the proposed proprietary name. They have no further objections.

2.3 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously identified names taking into account the change in product strength (b) (4) to 675 mg/2.4 mL. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The May 5, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name is acceptable.

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[a] Holmes, L. Proprietary Name Review for Aristada Initio (NDA 209830). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Nov 29. Panorama No. 2017-17295118.

[b] Holmes, L. Proprietary Name Review for Aristada Initio (NDA 209830). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Nov 29. Panorama No. 2017-17295118.

If you have any questions or need clarifications, please contact Phuong B. Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your submission, received on March 5, 2018, 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.

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/s/

LOLITA G WHITE on behalf of LORETTA HOLMES
05/26/2018

LOLITA G WHITE
05/26/2018

PROPRIETARY NAME MEMORANDUM

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

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Date of This Review:	November 29, 2017
Application Type and Number:	NDA 209830
Product Name and Strength:	Aristada Initio (aripiprazole lauroxil) extended release injectable suspension (b) (4)
Total Product Strength:	(b) (4)
Product Type:	Combination Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Alkermes, Inc.
Panorama #:	2017-17295118
DMEPA Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA Team Leader:	Lolita White, PharmD
DMEPA Deputy Director (Acting):	Danielle Harris, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Aristada Initio, which was found conditionally acceptable under IND 121179 on June 12, 2017.[a] We note that all product characteristics remain the same.

1.1 REGULATORY HISTORY

Aristada (aripiprazole lauroxil) extended release injectable suspension was approved on October 5, 2015 and is currently marketed in 441 mg/1.6 mL, 662 mg/2.4 mL, and 882 mg/3.2 mL strengths under NDA 207533. Alkermes Inc. proposed the proprietary name, Aristada Initio, under IND 121179, to introduce a new extended release injectable suspension for intramuscular injection to be used in conjunction with a single 30 mg dose of oral aripiprazole as an alternative to the 21 days of oral aripiprazole initiation regimen upon starting treatment with Aristada. The proposed name was found conditionally acceptable under IND 121179 on June 12, 2017.

Thus, Alkermes, Inc. submitted the proposed proprietary name, Aristada Initio, on August 31, 2017 for review under NDA 209830.

1.2 PRODUCT INFORMATION

The following Aristada Initio product information is provided in the August 31, 2017 proprietary name submission.

Table 1. Relevant Product Information for Aristada Initio and Aristada[b]

	Aristada Initio	Aristada
Intended Pronunciation	air-is-TAH-dah i-ni'-tee-oh	air-is-TAH-dah
Initial Approval Date	N/A	October 5, 2015
Active Ingredient	aripiprazole lauroxil	aripiprazole lauroxil
Indication	Treatment of schizophrenia	Treatment of schizophrenia
Route of Administration	Intramuscular injection (deltoid or gluteal)	Intramuscular injection in the deltoid (441 mg dose only) or gluteal (441 mg, 662 mg or 882 mg) muscle
Dosage Form	Extended release injectable suspension	Extended release injectable suspension

[a] Holmes L. Proprietary Name Review for Aristada Initio IND 121179. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2017 Jun 12. Panorama No. 2016-11908288.

[b] Aristada product information obtained online from DailyMed available at: https://dailymed.nlm.nih.gov/dailymed/index.cfm. Accessed on April 21, 2017.

<table>
<tr><th colspan="3">Table 1. Relevant Product Information for Aristada Initio and Aristada[b]</th></tr>
<tr><th></th><th>Aristada Initio</th><th>Aristada</th></tr>
<tr><td>Strength</td><td>(b) (4) /2.4 mL</td><td>441 mg/1.6 mL, 662 mg/2.4 mL, and 882 mg/3.2 mL</td></tr>
<tr><td>Dose and Frequency</td><td><table><tr><td>Usual Dosage</td><td>(b) (4)</td></tr><tr><td>Frequency of Administration</td><td>Single Dose</td></tr><tr><td>Dosing Interval</td><td>Single Dose</td></tr><tr><td>Maximum Daily Dose</td><td>(b) (4)</td></tr></table>
Aristada Initio is to be used in conjunction with a single 30 mg dose of oral aripiprazole as an alternative to the 21 days of oral aripiprazole initiation regimen upon starting treatment with Aristada.</td><td>Table 2: ARISTADA Doses Based on Oral Aripiprazole Total Daily Dose
<table><tr><th>Oral Aripiprazole Dose</th><th>Intramuscular ARISTADA Dose</th></tr><tr><td>10 mg per day</td><td>441 mg per month</td></tr><tr><td>15 mg per day</td><td>662 mg per month</td></tr><tr><td>20 mg or higher per day</td><td>882 mg per month</td></tr></table>
In conjunction with the first ARISTADA injection, administer treatment with oral aripiprazole for 21 consecutive days.</td></tr>
<tr><td>How Supplied</td><td>Pre-filled syringe supplied in a carton along with administration needles and instructions for use.</td><td>Kits containing 441 mg/1.6 mL, 662 mg/2.4 mL, or 882 mg/3.2 mL prefilled syringe and safety needles.</td></tr>
<tr><td>Storage</td><td>Store at room temperature, 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (59°F and 86°F).</td><td>Store at room temperature 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (between 59°F and 86°F).</td></tr>
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2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

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

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA performed an updated safety assessment of the proposed proprietary name considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The September 28, 2017 search of USAN stems did not find any USAN stems in the proposed proprietary name.

2.3 Comments from Other Review Disciplines During Review

In response to the OSE, September 13, 2017 email, the Division of Psychiatry Products (DPP) identified concerns about medication errors due to potential prescribing errors because Aristada Initio shares the same root name, same established name, [redacted] (b) (4) with Aristada.

However, no alternate proprietary naming strategy (e.g., use of a novel proprietary name or use of an alternate modifier) will address concerns such as:

- Confusion between future generics for Aristada and Aristada Initio.
- Inability to differentiate between Aristada and Aristada Initio when prescribed using the established name only, including use in information systems, such as a computerized order entry system (CPOE).

Additionally, alternate naming strategies do not appear to provide less risk when compared with the proposed proprietary name, and in some cases, may introduce new risks. Therefore, we find the proposed proprietary name, Aristada Initio, is a reasonable naming strategy for the proposed product.

The residual risks appear inherent to the product design, in that both products contain the same active ingredient [redacted] (b) (4), and we do not find that use of a different proprietary naming strategy would address the concerns inherent to this product design.

We suggest the review team consider additional mitigation strategies to differentiate the products, which could include:

- Further investigate the feasibility of using a different established name for either the proposed product or the currently marketed product.
- [redacted] (b) (4)
- Consider additional label/labeling mitigation strategies for both Aristada and Aristada Initio, such as labeling statements and descriptors that can be carried forth to future generics.
- Consider labeling statements indicating Aristada and Aristada Initio are not substitutable for one another.
- Engage the sponsor to develop an education campaign, including "Dear Health Care Provider" letters, or other outreach efforts.

2.4 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

DMEPA communicated our findings to the Division of Psychiatry Products (DPP) via e-mail on November 17, 2017. At that time, we also asked if the review team has any additional basis for objecting to the proposed proprietary name. Per e-mail correspondence from DPP on November 27, 2017, they stated no additional comments with the proposed proprietary name, Aristada Initio.

3 CONCLUSIONS

The proposed proprietary name is acceptable.

If you have any questions or need clarifications, please contact Phuong Nguyen, OSE Project Manager, at 240-402-5827.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your August 31, 2017 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.

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/s/

LOLITA G WHITE on behalf of LORETTA HOLMES
11/29/2017

LOLITA G WHITE
11/29/2017

DANIELLE M HARRIS
11/29/2017