CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219847Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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 30, 2025
Application Type and Number:	NDA 219847
Product Name, Dosage Form, and Strength:	Arynta (lisdexamfetamine dimesylate) oral solution, 10 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals, Inc. (Azurity)
PNR ID #:	2025-1044726404
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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1 INTRODUCTION

This review evaluates the proposed proprietary name, Arynta, 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. Azurity did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Azurity previously submitted the proposed proprietary name, [(b) (4)]*** under NDA 219847 on August 20, 2024. However, on October 25, 2024, we found the name, [(b) (4)]*** unacceptable due to misbranding concerns. [a]

Subsequently, Azurity submitted the proposed proprietary name, [(b) (4)]*** under NDA 219847 on December 19, 2024. However, on March 11, 2025, we found the name [(b) (4)]*** unacceptable due to orthographic similarities and overlapping product characteristics with the pending proprietary name, [(b) (4)]***, and orthographic similarities and overlapping product characteristics with the proprietary name, [(b) (4)]. [b]

Thus, Azurity submitted the proposed proprietary name, Arynta, for review on April 16, 2025 under NDA 219847.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on April 16, 2025[c] and the prescribing information received on November 6, 2024.[d]

Table 1. Relevant Product Information for Arynta	
Intended pronunciation:	AH-RIN-TAH
Active ingredient:	lisdexamfetamine dimesylate
Indication:	Treatment of: • Attention Deficit Hyperactivity Disorder (ADHD) in adults and pediatric patients 6 years and older • Moderate to severe binge eating disorder (BED) in adults
Dosage Form:	oral solution
Strength:	10 mg/mL

[a] Bao, A. Proprietary Name Review for [(b) (4)]*** (NDA 219847). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Oct 25. PNR ID No. 2024-1044725951.

[b] Bao, A. Proprietary Name Review for [(b) (4)]*** (NDA 219847). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 Mar 11. PNR ID No. 2024-1044726177.

[c] Request for Proprietary Name Review – Arynta (NDA 219847). Woburn (MA): Azurity Pharmaceuticals, Inc.; 2025 Apr 16. Available from: \\CDSESUB1\evsprod\NDA219847\0013\m1\us\m1-18-request-proprietary-name-review.pdf.

[d] Proposed prescribing information for Arynta. Woburn (MA): Azurity Pharmaceuticals, Inc.; 2024 Nov 06. Available from: \\CDSESUB1\evsprod\NDA219847\0004\m1\us\1-14-1-3-uspi-tracked-copy.docx.

Table 1. Relevant Product Information for Arynta	
Route of administration:	Oral
Dose and frequency:	ADHD: The recommended starting dosage in adults and pediatric patients 6 years and older is 30 mg once daily in the morning. Dosage may be adjusted in increments of 10 mg or 20 mg at approximately weekly intervals up to maximum recommended dosage of 70 mg once daily BED: The recommended starting dosage in adults is 30 mg once daily to be titrated in increments of 20 mg at approximately weekly intervals to achieve the recommended target dose of 50 mg to 70 mg once daily. The maximum recommended dosage is 70 mg once daily
How Supplied:	Clear colorless solution contains 10 mg/mL of lisdexamfetamine dimesylate. It is packaged in 100 mL PET bottle. Each sealed bottle is co-packaged with one press-in bottle adapter and one (b) (4) oral dispenser assembly (i.e., dosing syringe).
Storage:	Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). Keep the container tightly closed. Discard unused portion (b) (4) days after first opening
Listed Drug:	Vyvanse (lisdexamfetamine dimesylate) NDA 021977

2 DISCUSSION

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

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Arynta would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 1 (DMEPA 1) concurred with the findings of OPDP's assessment for Arynta. The Division of Psychiatry (DP) concurred with the findings of OPDP's assessment for Arynta.

2.2 SAFETY ASSESSMENT

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

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

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

[e] USAN stem search conducted on April 17, 2025.

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

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

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

The Division of Psychiatry (DP) did not forward any comments or concerns relating to Arynta at the initial phase of the review.

2.2.4 FDA PRESCRIPTION SIMULATION STUDIES

Eighty-eight (88) practitioners participated in FDA's prescription simulation studies for Arynta.

One respondent in the Computerized Prescription Order Entry (CPOE) study incorrectly selected the name (b) (4) ***. However, the participant entered an incorrect sequence of letters, (b) (4) when searching for the study name. As a result, the CPOE generated picklist did not contain Arynta as a choice. The participant proceeded to incorrectly select (b) (4) *** as their response after 14 seconds in order to proceed with the FDA prescription stimulation study. Thus, in this case, the study response is unlikely to be representative of a plausible CPOE based risk. Additionally, we identified (b) (4) *** as a proposed proprietary name for IND 077101 that was found unacceptable by DMEPA due to a conflict with a marketed product. Corresponding application NDA 215309 was subsequently approved under the proprietary name Opzelura. Thus, we determined the risk of name confusion is adequately minimized and placed (b) (4) *** in Appendix G.

The remaining 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 prescription simulation studies.

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[f] identified 101 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 provides the number of names retrieved from our POCA search and FDA Prescription Simulation Study. These name pairs are organized as highly similar, moderately similar, or low similarity for further evaluation.

[f] POCA search conducted on April 17, 2025 in version 5.12.6.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	4
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	88
Low similarity name pair: combined match percentage score ≤54%	10

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 102 names contained in Table 2 determined none of the names will pose a risk for confusion with Arynta as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On May 30, 2025, DMEPA 1 communicated our determination to the Division of Psychiatry (DP).

3 CONCLUSION

The proposed proprietary name, Arynta, is conditionally acceptable.

3.1 COMMENTS TO AZURITY PHARMACEUTICALS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 16, 2025, are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 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, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD 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 ONPD 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 3. 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.[g]

Table 3. 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.

[g] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

Table 3. 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 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, Cerner RxNorm, Purple Book, 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 (Tables 4-6) 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 that 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 4).
- 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[h]. 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 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) 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 also conducts prescription simulation studies using FDA health care professionals.

   Four 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, verbal pronunciation of the drug name or during computerized provider order entry. 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 vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name and ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[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

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.

Additionally, other review disciplines opinions such as OPQ 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 Safety Evaluator 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 4. 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 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?		

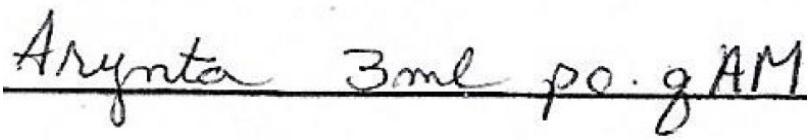
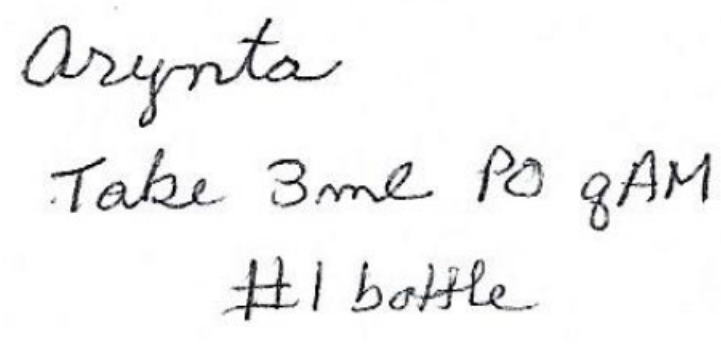
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses 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 with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such as vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	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 names appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. 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. Arynta Study (Conducted on 4/18/2025)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Arynta Take 3 mL by mouth every morning Dispense one bottle
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Arynta	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Arynta People Received Study: 161 People Responded: 88					
Total	23	24	19	22	88
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
(b) (4)	0	0	0	1	1
ARENTA	0	0	4	0	4
ARINTA	0	0	12	0	12
ARRENTA	0	0	1	0	1
ARYNTA	23	24	0	21	68
AURINTA	0	0	1	0	1
ORINTA	0	0	1	0	1

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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.	Arynta	100	This name is the subject of this review.
2.	Rynatan	74	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Cerinta	70	Orthographically, the prefixes of the name pair ("A-" *versus* "Ce-") appear different when scripted. Arynta contains the downstroke letter "y" in the third position, while Cerinta contains the dotted letter "i" in the fourth position, offering additional differences in the shape of the names when scripted. We note that Arynta is a Schedule II controlled substance. Controlled substances may only be prescribed verbally in emergency situations, and Arynta is indicated for the treatment of attention deficit hyperactivity disorder or binge eating disorder, which renders it inappropriate for emergency prescribing. Therefore, Arynta is unlikely to be subject of verbal orders as current practice guidelines for Schedule II drugs advise against verbal orders. Moreover, a prescription for Cerinta is likely to indicate a dispensing quantity of 1 or 3 packs, which is a common quantity specified for oral contraceptive packs. In contrast, a prescription for Arynta would require the specification of a quantity

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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.
			that would be greater than 1 to 3 dispensing units (for example, 90 mL). The products also differ in dose (30 mg, 40 mg, 50 mg, 60 mg, or 70 mg *versus* 1 tablet) which may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
4.	Rynesa	70	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.

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 (%)
1.	(b) (4) ***	64
2.	Rytary	60
3.	Breyna	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: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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.	Irenka	68	Orthographically, the names begin with different letters (A *versus* I). Arynta contains the downstroke letter "y" in the third position while Irenka does not, providing some differences in the shapes of the names when scripted. We note that Arynta is a Schedule II controlled substance. Controlled substances may only be prescribed verbally in emergency situations, and Arynta is indicated for the treatment of attention deficit hyperactivity disorder or binge eating disorder, which renders it inappropriate for emergency prescribing. Therefore, Arynta is unlikely to be subject of verbal orders as current practice guidelines for Schedule II drugs advise against verbal orders. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
2.	Ryzneuta	68	This name pair has sufficient orthographic and phonetic differences.
3.	Ery-Tab	66	This name pair has sufficient orthographic and phonetic differences.
4.	Salyntra	66	This name pair has sufficient orthographic and phonetic differences.
5.	Xyntha	66	This name pair has sufficient orthographic and phonetic differences.
6.	Alimta	64	Orthographically, Arynta contains the downstroke letter "y" in the third position, while Alimta contains the

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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
			upstroke letter "l" in the second position and a dotted letter "i" in the third position, providing some differences in the shapes of the names when scripted. We note that Arynta is a Schedule II controlled substance. Controlled substances may only be prescribed verbally in emergency situations, and Arynta is indicated for the treatment of attention deficit hyperactivity disorder or binge eating disorder, which renders it inappropriate for emergency prescribing. Therefore, Arynta is unlikely to be subject of verbal orders as current practice guidelines for Schedule II drugs advise against verbal orders. The products differ in dosage form (oral solution *versus* powder for injection), route (oral *versus* intravenous infusion), and frequency (every morning *versus* on Day 1 of each 21-day cycle for 4-6 cycles or until disease progression or unacceptable toxicity). These product characteristics may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
7.	Arymo	64	Orthographically, Arynta contains the upstroke letter "t" in the fifth position, while Arymo does not contain any upstroke letters, which provides some

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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
			differences in the shapes of the names when scripted. Additionally, Arymo is the root name of the product, while the full proprietary name is "Arymo ER", which would provide further orthographic differentiation from Arynta if the "ER" modifier is included on a medication order. Phonetically, the second syllables ("RIN" *versus* "ĩ") and third syllables ("TAH" *versus* "mow") sound different when spoken. The products differ in strength (10 mg/mL *versus* 15 mg, 30 mg, and 60 mg) and frequency of administration (every morning *versus* every 8 or 12 hours). These product characteristics may provide further differentiation if included on a medication order. Thus, in this specific case, the risk of name confusion between this name pair is minimized.
8.	Loryna	64	This name pair has sufficient orthographic and phonetic differences.
9.	Arnuity	63	This name pair has sufficient orthographic and phonetic differences.
10.	Alfenta	62	This name pair has sufficient orthographic and phonetic differences.
11.	Trental	62	This name pair has sufficient orthographic and phonetic differences.
12.	Mylanta	61	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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
13.	Antara	60	This name pair has sufficient orthographic and phonetic differences.
14.	Marten-Tab	60	This name pair has sufficient orthographic and phonetic differences.
15.	Nucynta	60	This name pair has sufficient orthographic and phonetic differences.
16.	Sarna	60	This name pair has sufficient orthographic and phonetic differences.
17.	Zantac	60	This name pair has sufficient orthographic and phonetic differences.
18.	Zantac 150	60	This name pair has sufficient orthographic and phonetic differences.
19.	Zantac 300	60	This name pair has sufficient orthographic and phonetic differences.
20.	Zantac 75	60	This name pair has sufficient orthographic and phonetic differences.
21.	Vantas	59	This name pair has sufficient orthographic and phonetic differences.
22.	Adzynma	58	This name pair has sufficient orthographic and phonetic differences.
23.	Arranon	58	This name pair has sufficient orthographic and phonetic differences.
24.	Artane	58	This name pair has sufficient orthographic and phonetic differences.
25.	Avinza	58	This name pair has sufficient orthographic and phonetic differences.
26.	Survanta	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Arynta Pronunciation: AH-RIN-TAH Established name: lisdexamfetamine dimesylate Dosage form: oral solution Strength: 10 mg/mL Dosage: 30 mg, 40 mg, 50 mg, 60 mg, or 70 mg by mouth every morning	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
27.	Zartan	58	This name pair has sufficient orthographic and phonetic differences.
28.	Aredia	56	This name pair has sufficient orthographic and phonetic differences.
29.	Arestin	56	This name pair has sufficient orthographic and phonetic differences.
30.	Arixtra	56	This name pair has sufficient orthographic and phonetic differences.
31.	Aventyl	56	This name pair has sufficient orthographic and phonetic differences.
32.	Ayuna	55	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 (%)
1.	N.T.A.	54
2.	(b) (4)***	54
3.	Rna	54
4.	R-Tanna	54
5.	R-Tanna 12	54
6.	Daytrana	53
7.	Mylanta Ar	51
8.	(b) (4)***	51
9.	***	49
10.	Tara-8	44

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.	Ryna-12	69	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
2.	Orlenta	68	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
3.	Rynessa	68	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
4.	Atryn	66	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
5.	(b) (4) ***	66	Proposed proprietary name for IND (b) (4) found unacceptable by DMEPA ((b) (4)) due to a conflict with a previously pending (now marketed) and a marketed name. Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable for IND (b) (4).
6.	Ryna C	65	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
7.	Ry-Tann	65	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
8.	Arymo	64	Brand discontinued with no generic equivalents available. Orange Book verified on May 14, 2025 that there are no AB-rated generic equivalents available. NDA 208603 withdrawn FR effective 02/07/2020.
9.	Arcapta	62	Arcapta is the root name for Arcapta Neohaler. Brand discontinued with no generic equivalents available. NDA 022383 withdrawn FR Effective 2/14/2025.
10.	Balanta	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
11.	Fybranta	62	International product formerly marketed in the United Kingdom
12.	Elantan	61	International product formerly marketed in multiple countries.
13.	Prantal	61	Brand discontinued with no generic equivalents available. NDA 008114 withdrawn FR effective 11/15/1990.
14.	Avant	60	International product formerly marketed in Malaysia.
15.	(b) (4) ***	60	Proposed proprietary name for IND (b) (4) found unacceptable, due to a conflict with a marketed product by DMEPA ((b) (4)).

No.	Name	POCA Score (%)	Failure preventions
			Subsequently, the proposed proprietary name (b) (4) *** was found conditionally acceptable under IND (b) (4) and the corresponding NDA (b) (4).
16.	(b) (4) ***	60	Proposed proprietary name for IND 064119 found unacceptable by DMEPA (OSE# 2017-12412628 dated February 23, 2017). NDA 210557 approved under the proprietary name Vyleesi.
17.	(b) (4) ***	60	Proposed proprietary name for IND 128177 found unacceptable by DMEPA (OSE #2019-30983314). NDA 213426 was approved under the name Seglentis.
18.	Zantac 25	60	Name identified in Drugs@FDA database and RxNorm database. Brand discontinued with no generic equivalents available. NDA 020251 withdrawn FR effective 11/3/2016.
19.	Ryna Cx	59	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
20.	Allent	58	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
21.	Drontal	58	Veterinary product.
22.	Taractan	58	Brand discontinued with no generic equivalents available. NDA 012486 (oral tablets) withdrawn FR effective 02/10/1997, NDA 012487 (injection) withdrawn FR effective 07/25/1997, and NDA 016149 (oral concentrate) withdrawn FR effective 10/31/1995.
23.	Trynate	58	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
24.	(b) (4) ***	57	Proposed proprietary name reviewed under IND (b) (4) as well as NDA (b) (4) Proposed proprietary name found to be unacceptable under NDA (b) (4) due to conflict with another pending name, Qulipta***, under review for NDA 215206. Subsequently, the name (b) (4) *** was withdrawn by the Applicant on (b) (4), under IND (b) (4). Moreover, the application for NDA 215206 was approved under the name Qulipta, thus, (b) (4) *** is no longer a viable name.
25.	(b) (4) ***	56	Proposed proprietary name withdrawn by the Applicant. NDA 216986 approved under the proprietary name Elucirem.
26.	Arovyn	56	Veterinary product.
27.	Arret	56	International product marketed in Ireland and the United Kingdom.

No.	Name	POCA Score (%)	Failure preventions
28.	(b) (4) ***	56	Proposed proprietary name for NDA (b) (4) found unacceptable by DMEPA (b) (4). NDA (b) (4) received a complete response on (b) (4) and did not respond to the Agency's No Response to Action Withdrawal Proposal sent on (b) (4) within 30 days, so the application is now considered withdrawn.
29.	Farydak	56	Brand discontinued with no generic equivalents available. NDA 205353 withdrawn FR effective 03/24/2022.
30.	(b) (4) ***	56	Proposed proprietary name for NDA 214200 found unacceptable by DMEPA (OSE# 2020-40716682). NDA 214200 approved under the proprietary name Cosela.
31.	(b) (4) ***	56	Proposed proprietary name for IND 047857 found unacceptable by DMEPA due to a conflict with a marketed product (OSE# 2016-11005567 dated February 2, 2017). Corresponding NDA 209229 was approved on May 16, 2018, under the proprietary name Lucemyra.
32.	(b) (4) ***	26	See FMEA in Section 2.2.4

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

No.	Name	POCA Score (%)
1.	Rantec	64
2.	(b) (4) ***	62
3.	(b) (4) ***	61
4.	Durysta	60
5.	Ryvent	60
6.	Eprontia	58
7.	Larin 24 Fe	58
8.	Larin Fe 1.5/30	58
9.	Larin Fe 1/20	58
10.	Zarontin	58
11.	Erypar	57

[i] 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 (%)
12.	Orencia	57
13.	(b) (4) ***	57
14.	(b) (4) ***	56
15.	Pyrantel	56
16.	Radent	56
17.	Rebyota	56
18.	Rinate	56
19.	Rinatec	56
20.	Symtan	56
21.	Treanda	56
22.	Dryptal	55

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PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 1 (DMEPA 1)
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:	March 11, 2025
Application Type and Number:	NDA 219847
Product Name, Dosage Form, and Strength:	(b) (4) (lisdexamfetamine dimesylate) oral solution, 10 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals, Inc. (Azurity)
PNR ID #:	2024-1044726177
DMEPA 1 Safety Evaluator:	Amy J. Bao, PharmD, MPH
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP
DMEPA 1 Associate Director for Nomenclature and Labeling:	Idalia E. Rychlik, PharmD

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