CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219847Orig1s000

OTHER REVIEW(S)

MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

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)

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Date of This Review:	June 16, 2025
Requesting Office or Division:	Division of Psychiatry (DP)
Application Type and Number:	NDA 219847
Product Name, Dosage Form, and Strength:	Arynta (lisdexamfetamine dimesylate) oral solution, 10 mg/mL
Applicant Name:	Azurity Pharmaceuticals, Inc.
FDA Received Date:	June 13, 2025
TTT ID #:	2024-10755-1
DMEPA 1 Safety Evaluator:	Neha Kumar, PharmD
DMEPA 1 Team Leader:	Matthew Barlow, RN, BSN

1 PURPOSE OF MEMORANDUM

Azurity Pharmaceuticals, Inc. submitted revised instructions for use (IFU) and revisions to the oral dosing syringe, received on June 13, 2025 for Arynta. The Division of Psychiatry (DP) requested that we review the IFU and oral dosing syringe revisions for Arynta (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous use-related risk analysis and comparative analyses review.[a]

2 CONCLUSION

Azurity Pharmaceuticals, Inc. implemented all of our recommendations, and we have no additional recommendations at this time.

[a] Kumar, N. Use-Related Risk Analysis and Comparative Analyses for Lisdexamfetamine (NDA 219847). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 May 14. TTT ID: 2024-10755.

APPENDIX A. REVISED INSTRUCTIONS FOR USE AND ORAL DOSING SYRINGE RECEIVED ON JUNE 13, 2025

The instructions for use can be accessed via EDR:
\\CDSESUB1\EVSPROD\nda219847\0018\m1\us\nda219847-arynta-ifu-06122025-clean-copy.docx

Oral dosing syringe changes can be accessed via EDR:
\\CDSESUB1\EVSPROD\nda219847\0018\m1\us\annexure-3-response-to-lbl.pdf

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/s/

NEHA KUMAR
06/16/2025 07:56:05 AM

MATTHEW J BARLOW
06/16/2025 08:11:29 AM

MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

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)

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Date of This Review:	June 12, 2025
Requesting Office or Division:	Division of Psychiatry (DP)
Application Type and Number:	NDA 219847
Product Name, Dosage Form, and Strength:	Arynta (lisdexamfetamine dimesylate) oral solution, 10 mg/mL
Applicant Name:	Azurity Pharmaceuticals, Inc.
FDA Received Date:	June 9, 2025
TTT ID #:	2024-10608-1
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP

1 PURPOSE OF MEMORANDUM

Azurity Pharmaceuticals, Inc. submitted revised container label and carton labeling received on June 9, 2025 for Arynta. The Division of Psychiatry (DP) requested that we review the revised container label and carton labeling for Arynta (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to recommendations that we made during a previous label and labeling review.[a]

2 CONCLUSION

Azurity Pharmaceuticals, Inc. implemented all of our recommendations and we have no additional recommendations at this time.

[a] Holmes, L. Label and Labeling Review for Lisdexamfetamine Dimesylate Oral Solution (NDA 219847). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 May 27. TTT ID: 2024-10608.

1 Page(s) of Draft Labeling has been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

LORETTA HOLMES
06/12/2025 10:05:35 AM

YEVGENIYA M KOGAN
06/12/2025 10:08:45 AM

LABEL AND LABELING 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 27, 2025
Requesting Office or Division:	Division of Psychiatry (DP)
Application Type and Number:	NDA 219847
Product Name, Dosage Form, and Strength:	Lisdexamfetamine Dimesylate[a] Oral Solution, 10 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Prescription (Rx)
Applicant Name:	Azurity Pharmaceuticals, Inc.
FDA Received Date:	August 16, 2024 and November 6, 2024
TTT ID #:	2024-10608
DMEPA 1 Safety Evaluator:	Loretta Holmes, BSN, PharmD
DMEPA 1 Team Leader:	Yevgeniya Kogan, PharmD, BCSCP

[a] A proposed proprietary name was submitted for this product on 4/16/2025 and is currently under review.

1 INTRODUCTION

As part of the approval process for Lisdexamfetamine Dimesylate Oral Solution, the Division of Psychiatry (DP) requested that we review the proposed Lisdexamfetamine Dimesylate Prescribing Information (PI), Medication Guide (MG), Instructions for Use (IFU), container label, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

Lisdexamfetamine Dimesylate is a proposed 505(b)(2) drug product and the Listed Drug (LD) is Vyvanse (lisdexamfetamine dimesylate), NDA 021977.

2 MATERIALS CONSIDERED

This section lists the materials considered for our review.

Table 1. Materials Considered for this Review	
Materials Considered	Appendix Section
Relevant Product Information	A
Label and Labeling	B

3 CONCLUSION

We evaluated the proposed Lisdexamfetamine Dimesylate Prescribing Information (PI)[b] and focused on Section 2 Dosage and Administration, Section 3 Dosage Forms and Strengths, Section 16 How Supplied/Storage and Handling, and Section 17 Patient Counseling Information.

Our evaluation of Section 16 noted that unused TRADENAME should be discarded (b) (4) after opening the bottle. We notified the Division of Psychiatry that this is a short expiration date for the product given the pharmacist may have to use the 100 mL bottle as a bulk bottle (rather than dispensing the entire unopened bottle to the patient) since there is no dose that amounts to 100 mL over a (b) (4) period and the product is a controlled substance (dispensing more drug than prescribed would be considered diversion of a controlled substance and alternatively dispensing a partial, in some instances, creates significant waste of the product). We defer to the Division to address this issue. For Section 17, we collaborated with the review team to make some minor editorial changes.

We note that the DMEPA 1 Human Factors Team and the Patient Labeling Team have reviewed the IFU and the Patient Labeling Team has reviewed of the MG. We defer to their recommendations and have no additional comments.

We evaluated the container label and carton labeling and noted they may be improved to promote the safe use of this product from a medication error perspective. We provide the identified medication error issues, our rationale for concern, and our proposed

[b] We also reviewed the PI received on November 6, 2024 and revised (working document) by the Division of Psychiatry as of May 21, 2025.

recommendations to minimize the risk for medication error for Azurity Pharmaceuticals, Inc. in Section 4.

4 RECOMMENDATIONS FOR AZURITY PHARMACEUTICALS, INC.

Table 2. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Label and Carton Labeling			
1.	The proposed proprietary name "(b) (4) is included on the container label and carton labeling.	The proposed proprietary name "(b) (4) was found unacceptable by the Agency as communicated in our November 6, 2024, Proprietary Name Request Unacceptable letter.	Replace all references to "(b) (4) with the placeholder "TRADENAME". Once a proprietary name is found conditionally acceptable, you can then replace the placeholder "TRADENAME" with the conditionally acceptable proprietary name and submit the revised labeling for Agency review.
2.	The NDC number is too prominent.	The NDC number should not compete in prominence with critical information (e.g., proprietary name, established name, strength, route of administration) on the principal display panel.	Unbold the net quantity statement.
3.	The controlled substance symbol is too prominent.	The controlled substance symbol should not compete in prominence with critical information (e.g., proprietary name, established name, strength, route of administration) on the principal display panel.	Decrease the size of the controlled substance symbol and consider relocating it to a less prominent location.
4.	The Medication Guide (MG) statement states, "Medication Guide available at: (b) (4).com." However, the "This carton	The Medication Guide statement is not consistent with the carton contents information.	Please clarify the MG statement. Ensure the Medication Guide statement appears in accordance with 21 CFR 208.24(d).

Table 2. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
	contains" information indicates it is supplied in the carton.		Consider revising the statement to read "Dispense enclosed Medication Guide to each patient. Medication Guide is also available at: (b) (4).com."
Container Label			
1.	The "Rx Only" and net quantity statements are too prominent and are distracting in their current position.	The "Rx Only" and net quantity statements should not compete in prominence with critical information (e.g., proprietary name, established name, strength, route of administration) on the principal display panel.	Unbold the "Rx Only" and net quantity statements and consider moving and positioning them below the MG statement.
Carton Labeling			
1.	The "Rx Only" and net quantity statements are too prominent and are distracting in their current position.	The "Rx Only" and net quantity statements should not compete in prominence with critical information (e.g., proprietary name, established name, strength, route of administration) on the principal display panel.	Unbold the net quantity statement and consider moving and positioning the "Rx Only" statement and net quantity statements below the Medication Guide (MG) statement on the back panel and below the carton contents information on the Principal Display Panel (PDP).
2.	Under "This carton contains" the terminology (b) (4) (b) (4) is inconsistent with the terminology in the Prescribing Information. Additionally, the Instructions for Use (IFU) is not included in the list.	The terminology should be consistent with the terminology in the Prescribing Information (PI). Also, the IFU should be included in the list.	Revise the (b) (4) terminology and add the IFU to the list as follows: (b) (4) (1) Prescribing Information and Medication Guide (b) (4) (1) Instructions for Use

APPENDICES: MATERIALS CONSIDERED FOR THIS REVIEW

APPENDIX A. RELEVANT PRODUCT INFORMATION

Table 3 presents relevant product information for Lisdexamfetamine Dimesylate received on November 6, 2024 from Azurity Pharmaceuticals, Inc., and the Listed Drug (LD).

Table 3. Relevant Product Information for Lisdexamfetamine Dimesylate and the Listed Drug (LD).

Product Name	Lisdexamfetamine Dimesylate	Vyvanse[c] (NDA 021977)
Initial Approval Date	N/A	02/23/2007
Active Ingredient	lisdexamfetamine dimesylate	
Indication	• 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	Capsules Chewable Tablets
Strength(s)	10 mg/mL	(b) (4): 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg Chewable Tablets: 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg
Route of Administration	Oral	
Dose and Frequency	<table><tr><th>Indicated Population</th><th>Initial Dose</th><th>Titration Schedule</th><th>Recommended Dose</th><th>Maximum Dose</th></tr><tr><td>ADHD (Adults and pediatric patients 6 years and older)</td><td>30 mg every morning</td><td>10 mg or 20 mg weekly</td><td>30 mg to 70 mg per day</td><td>70 mg per day</td></tr><tr><td>BED (Adults)</td><td>30 mg every morning</td><td>20 mg weekly</td><td>50 mg to 70 mg per day</td><td>70 mg per day</td></tr></table> Renal Impairment:	
How Supplied	TRADENAME oral solution is a clear colorless solution contains 10 mg/mL of lisdexamfetamine dimesylate. It is packaged in 100 mL PET bottle as follows:	Vyvanse (lisdexamfetamine dimesylate) capsules: • Vyvanse capsules 10 mg: pink body/pink cap (imprinted with S489 and 10 mg), bottles of 100, NDC 59417-101-10

[c] Vyvanse [Prescribing Information]. DailyMed. U.S. National Library of Medicine. Oct 2023. [Cited 2025 May 08]. Available from: https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=704e4378-ca83-445c-8b45-3cfa51c1ecad&type=pdf.

<table>
<tr><th colspan="3">Table 3. Relevant Product Information for Lisdexamfetamine Dimesylate and the Listed Drug (LD).</th></tr>
<tr><td>Product Name</td><td>Lisdexamfetamine Dimesylate</td><td>Vyvanse[c] (NDA 021977)</td></tr>
<tr><td></td><td>Each sealed bottle is co-packaged with one press-in bottle adapter and one (b) (4) oral dispenser assembly (i.e., dosing syringe).
<table>
<tr><th>NDC Number</th><th>Size</th></tr>
<tr><td>24338-019-01</td><td>100 mL</td></tr>
</table></td><td>• Vyvanse capsules 20 mg: ivory body/ivory cap (imprinted with S489 and 20 mg), bottles of 100, NDC 59417-102-10
• Vyvanse capsules 30 mg: white body/orange cap (imprinted with S489 and 30 mg), bottles of 100, NDC 59417-103-10
• Vyvanse capsules 40 mg: white body/blue green cap (imprinted with S489 and 40 mg), bottles of 100, NDC 59417-104-10
• Vyvanse capsules 50 mg: white body/blue cap (imprinted with S489 and 50 mg), bottles of 100, NDC 59417-105-10
• Vyvanse capsules 60 mg: aqua blue body/aqua blue cap (imprinted with S489 and 60 mg), bottles of 100, NDC 59417-106-10
• Vyvanse capsules 70 mg: blue body/orange cap (imprinted with S489 and 70 mg), bottles of 100, NDC 59417-107-10
Vyvanse (lisdexamfetamine dimesylate) chewable tablets:
• Vyvanse chewable tablets 10 mg: White to off-white round shaped tablet debossed with '10' on one side and 'S489' on the other, bottles of 100, NDC 59417-115-01
• Vyvanse chewable tablets 20 mg: White to off-white hexagonal shaped tablet debossed with '20' on one side and 'S489' on the other,</td></tr>
</table>

Table 3. Relevant Product Information for Lisdexamfetamine Dimesylate and the Listed Drug (LD).		
Product Name	Lisdexamfetamine Dimesylate	Vyvanse[c] (NDA 021977)
		bottles of 100, NDC 59417-116-01 • Vyvanse chewable tablets 30 mg: White to off-white arc triangular shaped tablet debossed with '30' on one side and 'S489' on the other, bottles of 100, NDC 59417-117-01 • Vyvanse chewable tablets 40 mg: White to off-white capsule shaped tablet debossed with '40' on one side and 'S489' on the other, bottles of 100, NDC 59417-118-01 • Vyvanse chewable tablets 50 mg: White to off-white arc square shaped tablet debossed with '50' on one side and 'S489' on the other, bottles of 100, NDC 59417-119-01 • Vyvanse chewable tablets 60 mg: White to off-white arc diamond shaped tablet debossed with '60' on one side and 'S489' on the other, bottles of 100, NDC 59417-120-01
Storage	TRADENAME is stored at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep the container tightly closed. Discard unused portion (b) (4) after first opening.	Dispense in a tight, light-resistant container as defined in the USP. Store at room temperature, 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C and 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Container Closure	Child-resistant closure	

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APPENDIX B. LABEL AND LABELING

B.1 List of Label and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[d] along with postmarket medication error data, we reviewed the following Lisdexamfetamine Dimesylate label and labeling submitted by Azurity Pharmaceuticals, Inc.

- Prescribing Information (no image), received on November 6, 2024, available from \\Cdsesub1\evsprod\NDA219847\0004\m1\us.
- Medication Guide (no image), received on August 16, 2024, available from \\CDSESUB1\EVSPROD\nda219847\0001\m1\us\medication-guide.pdf
- Instructions for Use (no image), received on November 6, 2024, available from \\Cdsesub1\evsprod\NDA219847\0004\m1\us.
- Container label, received on November 6, 2024, available from \\Cdsesub1\evsprod\NDA219847\0004\m1\us.
- Carton labeling, received on November 6, 2024, available from \\Cdsesub1\evsprod\NDA219847\0004\m1\us.

B.2 Container Label and Carton Labeling Images (not to scale)

Container Label:

[d] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

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/s/

LORETTA HOLMES
05/27/2025 01:59:37 PM

YEVGENIYA M KOGAN
05/28/2025 09:06:23 AM

Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Medical Policy

PATIENT LABELING REVIEW

Date:	May 15, 2025
To:	Pawanprit (Pinky) Singh, PharmD Regulatory Project Manager **Division of Psychiatry (DP)**
Through:	Barbara Fuller, RN, MSN Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Ruth Mayrosh, PharmD Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Emily Foltz, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Medication Guide (MG) and Instructions for Use (IFU)
Drug Name (established name):	TRADENAME (lisdexamfetamine dimesylate)
Dosage Form and Route:	Oral Solution, CII
Application Type/Number:	NDA 219847
Applicant:	Azurity Pharmaceuticals, Inc.

1 INTRODUCTION

On August 16, 2024, Azurity Pharmaceuticals, Inc. submitted for the Agency's review a 505(b)(2) New Drug Application (NDA) 219847 for TRADENAME (lisdexamfetamine dimesylate) Oral Solution. The Reference Listed Drug (RLD) for this application is NDA 021977 for VYVANSE (lisdexamfetamine dimesylate) capsules, for oral use, CII. The proposed indications for TRADENAME (lisdexamfetamine dimesylate) are for the 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.

This collaborative review is written by the Division of Medical Policy Programs (DMPP) and the Office of Prescription Drug Promotion (OPDP) in response to a request by the Division of Psychiatry (DP) on September 26, 2024, for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG) and Instructions for Use (IFU) for TRADENAME (lisdexamfetamine dimesylate) Oral Solution.

DMPP conferred with the Division of Medication Error, Prevention, and Analysis (DMEPA) and a separate DMEPA review of the IFU will be forthcoming.

2 MATERIAL REVIEWED

- Draft TRADENAME (lisdexamfetamine dimesylate) Oral Solution MG received on August 16, 2024, and received by DMPP and OPDP on May 6, 2025.
- Draft TRADENAME (lisdexamfetamine dimesylate) Oral Solution IFU received on December 23, 2024, and received by DMPP and OPDP on May 6, 2025.
- Draft TRADENAME (lisdexamfetamine dimesylate) Oral Solution Prescribing Information (PI) received on August 16, 2024, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on May 6, 2025.
- Approved VYVANSE (lisdexamfetamine dimesylate) capsules, for oral use, CII and VYVANSE (lisdexamfetamine dimesylate) chewable tablets, for oral use, CII comparator labeling dated October 13, 2023.

3 REVIEW METHODS

To enhance patient comprehension, materials should be written at a 6th to 8th grade reading level, and have a reading ease score of at least 60%. A reading ease score of 60% corresponds to an 8th grade reading level. In our review of the IFU the target reading level is at or below an 8th grade level.

Additionally, in 2008 the American Society of Consultant Pharmacists Foundation (ASCP) in collaboration with the American Foundation for the Blind (AFB) published *Guidelines for Prescription Labeling and Consumer Medication Information for People with Vision Loss*. The ASCP and AFB recommended using fonts such as Verdana, Arial or APHont to make medical information more accessible for patients with vision loss. We reformatted the MG and IFU documents using the Arial font, size 10.

In our collaborative review of the MG and IFU we:

- simplified wording and clarified concepts where possible

- ensured that the MG and IFU are consistent with the PI
- removed unnecessary or redundant information
- ensured that the MG and IFU are free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the MG meets the Regulations as specified in 21 CFR 208.20
- ensured that the MG meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the IFU meets the criteria as specified in both the FDA Guidance for Useful Written Consumer Medication Information (published July 2006) and Instructions for Use-Patient Labeling for Human Prescription Drug and Biological Products (published July 2022)
- ensured that the MG is consistent with the approved comparator labeling where applicable

4 CONCLUSIONS

The MG and IFU are acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the MG and IFU is appended to this memorandum. Consult DMPP and OPDP regarding any additional revisions made to the PI to determine if corresponding revisions need to be made to the MG and IFU.

Please let us know if you have any questions.

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/s/

RUTH I MAYROSH
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EMILY M FOLTZ
05/15/2025 02:47:48 PM

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Office of Prescription Drug Promotion

****Pre-decisional Agency Information****

Memorandum

Date: May 15, 2025

To: Pawanprit (Pinky) Singh, PharmD, Senior Regulatory Project Manager, Division of Psychiatry (DP)

Anna Weissman, MD, Clinical Reviewer, DP

From: Emily Foltz, PharmD, RPh, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Taylor Burnett Mmagu, PharmD, RAC, Team Leader, OPDP

Subject: OPDP Labeling Comments for TRADENAME (lisdexamfetamine dimesylate) Oral Solution

NDA: 219847

Background:
In response to DP's consult request dated September 26, 2024, OPDP has reviewed the proposed Prescribing Information (PI), Medication Guide, Instructions for Use (IFU), and carton and container labeling for the original NDA submission for TRADENAME (lisdexamfetamine dimesylate) Oral Solution.

PI, Medication Guide, and IFU:
OPDP's review of the proposed PI is based on the draft labeling accessed from SharePoint on May 6, 2025, and our comments are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed for the proposed Medication Guide and IFU, and comments were sent under separate cover on May 15, 2025.

Carton and Container Labeling:
OPDP's review of the proposed carton and container labeling is based on the draft labeling submitted by the sponsor to the electronic document room on April 16, 2025, and we do not have any comments at this time.

Thank you for your consult. If you have any questions, please contact Emily Foltz at 301-796-2939 or Emily.Foltz@fda.hhs.gov.

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/s/

EMILY M FOLTZ
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USE-RELATED RISK ANALYSIS AND COMPARATIVE ANALYSES 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 14, 2025
Requesting Office or Division:	Division of Psychiatry (DP)
Application Type and Number:	NDA 219847
Product Name, Dosage Form and Strength:	lisdexamfetamine[1] oral solution, 10 mg/mL
Product Type:	Combination Product (Drug-Device)
Rx or OTC:	Rx
Device Constituent:	Oral syringe and bottle
Applicant/Sponsor Name:	Azurity Pharmaceuticals, Inc.
Submission Date:	August 16, 2024; November 6, 2024
OSE TTT #:	2024-10755
DMEPA 1 Safety Evaluator:	Neha Kumar, PharmD
DMEPA 1 Team Leader:	Matthew Barlow, RN, BSN
DMEPA 1 Associate Director for Human Factors:	Ariane O. Conrad, PharmD, BCACP, CDCES, FISMP

[1] The proprietary name for this product has not yet been determined. Therefore, only the established name, lisdexamfetamine, is used in this review.

1 REASON FOR REVIEW

The review evaluates the use-related risk analysis (URRA) and comparative analyses submitted under NDA 219847 for lisdexamfetamine oral solution to determine whether the Applicant needs to submit human factors (HF) validation study results to support their marketing application.

1.1 MATERIALS CONSIDERED

We considered the materials listed in Table 1 for this review.

Table 1. Materials Considered for this Review	
Materials Considered	**Section/Appendix**
Relevant Product Information	Section 1.2
Relevant Regulatory History Related to Lisdexamfetamine's Human Factors Development Program	Section 1.3
Use-Related Risk Analysis and Comparative Analyses	Appendix A
Information Requests Issued During the Review	Appendix B
Product Samples, Labels, and Labeling	Appendix C

N/A=not applicable for this review

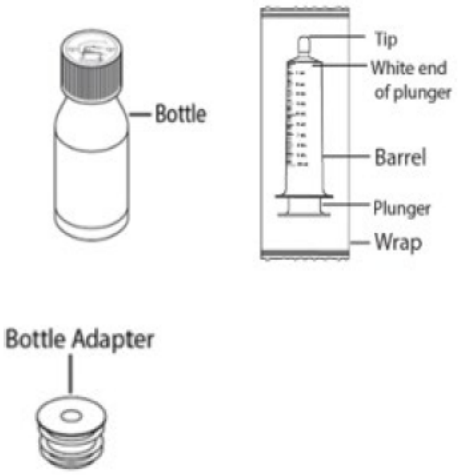
1.2 RELEVANT PRODUCT INFORMATION

Table 2. Relevant Product Information for lisdexamfetamine and Onyda XR		
Product Name	lisdexamfetamine	Onyda XR[2]
Application Number	NDA 219847	NDA 217645
Initial Approval Date	N/A	May 24, 2024
Active Ingredient	lisdexamfetamine	clonidine hydrochloride
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. Limitations of Use:	Treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older.

[2] Onyda XR [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. DEC 2024. [cited 2025 APR 18]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217645s001lbl.pdf.

<table>
<tr><th colspan="3">Table 2. Relevant Product Information for lisdexamfetamine and Onyda XR</th></tr>
<tr><td></td><td>Pediatric patients with ADHD younger than 6 years of age experienced more long-term weight loss than patients 6 years and older.
Lisdexamfetamine is not indicated for weight loss. Use of other sympathomimetic drugs for weight loss has been associated with serious cardiovascular adverse events. The safety and effectiveness of lisdexamfetamine for the treatment of obesity have not been established</td><td></td></tr>
<tr><td>Route of Administration</td><td colspan="2">oral</td></tr>
<tr><td>Dosage Form</td><td>oral solution</td><td>extended-release oral suspension</td></tr>
<tr><td>Strength</td><td>10 mg/mL</td><td>0.1 mg/mL</td></tr>
<tr><td>Dose and Frequency</td><td>
<table>
<tr><th>Indicated Population</th><th>Initial Dose</th><th>Titration Schedule</th><th>Recomm-ended Dose</th><th>Maximum Dose</th></tr>
<tr><td>ADHD (Adults and pediatric patients 6 years and older)</td><td>30 mg every morning</td><td>10 mg or 20 mg weekly</td><td>30 mg to 70 mg per day</td><td>70 mg per day</td></tr>
<tr><td>BED (Adults)</td><td>30 mg every morning</td><td>20 mg weekly</td><td>50 mg to 70 mg per day</td><td>70 mg per day</td></tr>
</table>
</td><td>Starting dosage is 0.1 mg of Onyda XR orally once daily at bedtime with or without food. Dosage may be increased in increments of 0.1 mg per day at weekly intervals. Maximum recommended dosage is 0.4 mg once daily at bedtime.
Do not substitute Onyda XR for other clonidine products on a mg-per-mg basis because of differing pharmacokinetic profiles.
When discontinuing, taper the dose in decrements of no more than 0.1 mg every 3 to 7 days to avoid rebound hypertension.</td></tr>
</table>

Table 2. Relevant Product Information for lisdexamfetamine and Onyda XR		
How Supplied	• Lisdexamfetamine oral solution is a clear, colorless solution containing 10 mg/mL of lisdexamfetamine dimesylate. It is packaged in a 100 mL sealed bottle that is co-packaged with one press-in bottle adapter and one (b) (4) oral dosing syringe.	• Onyda XR (clonidine hydrochloride) extended-release oral suspension 0.1 mg/mL is a light beige to tan viscous suspension. • Onyda XR is supplied in a bottle of 30 mL (NDC 24478-148-03) and a bottle of 60 mL (NDC 24478-148-04) with a child-resistant closure that is packaged in a carton with one oral dosing dispenser and one press in bottle adapter each and in a bottle of 120 mL (NDC 24478-148-02) with a child-resistant closure that is packaged in a carton with two oral dosing dispensers and two press in bottle adapters.
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) [see USP Controlled Room Temperature]. • Keep the bottle tightly closed. • Discard any unused lisdexamfetamine remaining after (b) (4) of first opening the bottle.	• 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) [see USP Controlled Room Temperature]. • Protect from light. • Store and dispense Onyda XR in the original bottle. • Dispense with bottle adapter and oral dosing dispenser supplied in the carton. • Discard any unused Onyda XR remaining in the bottle after 60 days of first opening the bottle.

Table 2. Relevant Product Information for lisdexamfetamine and Onyda XR		
Container Closure/Device Constituent		
Intended Users	Patients; caregivers; healthcare professionals (HCPs)	
Intended Use Environment(s)	Home; clinic	

1.3 RELEVENT REGULATORY HISTORY RELATED TO LISDEXAMFETMINE'S HUMAN FACTORS DEVELOPMENT PROGRAM

On April 21, 2025, we searched for previous DMEPA reviews and FDA/Applicant interactions relevant to this current review using the terms, "Azurity" and "NDA 219847". We did not identify previous reviews or interactions relevant to this current review.

On August 16, 2024, the Applicant submitted HF data for their application for lisdexamfetamine oral solution under NDA 219847. However, we noted multiple HF validation study methodology issues and use issues. Thus, on October 16, 2024, we issued an information request asking the Applicant to revisit their HF validation study results, subjective feedback, and root cause analysis for all tasks, and implement risk controls to the user interface (i.e., instructions for use, carton labeling, container label, etc.) to address these issues. Additionally, since we noted that models of same or similar combination products exist, we asked the Applicant to select a comparator product that has the same use/indication, users, and use environment and align their user interface, including the instructions for use, carton labeling, and container label. We also recommended that the Applicant conduct comparative analyses of the proposed product and the selected comparator product and to submit their comparative analyses, URRA, and any revised labels and labeling, for our review.

On November 6, 2024, the Applicant submitted their URRA and comparative analyses between their proposed lisdexamfetamine oral solution and US-licensed Onyda XR (clonidine hydrochloride) extended-release oral suspension. The URRA and comparative analyses are the subjects of this review.

2 OVERALL ASSESSMENT OF MATERIALS REVIEWED

The sections below provide our evaluation of the URRA and comparative analyses.

2.1 USE-RELATED RISK ANALYSIS

The Applicant submitted a URRA for their proposed product, lisdexamfetamine oral solution.

We reviewed the URRA for the proposed product and, based on the information we have at this time, the tasks evaluated appear to be comprehensive and appropriate based on what the Applicant proposes for the design and intended use of this product.

We did not identify any additional use-related issues that were not analyzed, and we determined the risks are mitigated by the proposed labels and labeling.

2.2 COMPARATIVE ANALYSES

The Applicant compared their lisdexamfetamine user interface to the Onyda XR (clonidine hydrochloride) extended-release oral suspension user interface.

Consideration	Same	Different	Discussion of Differences
Indication	☐	☒	Both products are indicated for treatment of ADHD in patients 6 years in age and older. Lisdexamfetamine also includes an indication for moderate to severe BED in adults.
Intended user population	☒	☐	
Use environment	☒	☐	
Dosing	☐	☒	The dosing for lisdexamfetamine ranges from 3 mL to 7 mL once daily in the morning and the dosing for Onyda XR ranges from 1 mL to 4 mL once daily at bedtime. However, both products are copackaged with a dosing syringe with graduations on the barrel. Therefore, this difference does not affect the critical task of drawing up and administering a dose.
Route of administration	☒	☐	
Strength	☐	☒	Lisdexamfetamine strength is 10 mg/mL whereas Onyda XR's strength is 0.1 mg/mL. However, both products are administered using a copackaged oral dosing syringe with graduations on its barrel; thus, this difference does not affect the critical task of drawing up and administering a dose.

2.2.1 PHYSICAL COMPARISON

<table>
<tr><th>Consideration</th><th>Yes</th><th>No</th><th>N/A</th><th>Discussion of “Other” Design Differences</th></tr>
<tr><td>Are there “other” design differences identified?</td><td>☒</td><td>☐</td><td></td><td>Applicant identified:
Bottle, oral syringe, and adapter measurement differences:
<table>
<tr><th></th><th>Lisdexam-fetamine</th><th>Onyda XR</th></tr>
<tr><td>Total bottle height</td><td>4.4375 in</td><td>4.125 in</td></tr>
<tr><td>Cap dimensions</td><td>0.9375 in x 1.25 in</td><td>0.6875 in x 1.125 in</td></tr>
<tr><td>Bottle bottom to neck height</td><td>3.3125 in</td><td>3.25 in</td></tr>
<tr><td>Bottle neck height</td><td>0.875 in</td><td>0.667 in</td></tr>
<tr><td>Bottle bottom width</td><td>1.59375 in</td><td>1.6875 in</td></tr>
<tr><td>Bottle adapter dimensions</td><td>0.625 in x 0.9375 in</td><td>0.625 in x 0.8125 in</td></tr>
<tr><td>Oral syringe length with plunger pushed in</td><td>3.6875 in</td><td>3.5625 in</td></tr>
<tr><td>Oral syringe length with plunger pulled out</td><td>6 in</td><td>5.75 in</td></tr>
<tr><td>Oral syringe barrel length</td><td>3.125 in</td><td>3.25 in</td></tr>
<tr><td>Oral syringe width</td><td>0.625 in</td><td>0.4375 in</td></tr>
<tr><td>Oral syringe plunger head diameter</td><td>1 in</td><td>0.8125 in</td></tr>
<tr><td>Oral syringe bottom of barrel width</td><td>0.8125 in</td><td>0.625 in</td></tr>
<tr><td>Oral syringe top of barrel width</td><td>0.625 in</td><td>0.4375 in</td></tr>
<tr><td>Distance between</td><td>0.1125 in</td><td>0.1875 in</td></tr>
</table></td></tr>
</table>

Consideration	Yes	No	N/A	Discussion of "Other" Design Differences
				graduations on oral syringe | | DMEPA Identified: • The numerical graduation markings on the lisdexamfetamine oral syringe are oriented upside down when the tip is facing upwards, whereas the numerical graduation markings on the Onyda XR oral syringe are oriented right side up when the tip is facing upwards.
Are the identified "other" design differences likely to negatively impact users' ability to complete the critical tasks needed to use this product safely and effectively as compared to Onyda XR?	☐	☒	☐	• The Applicant categorizes the measurement differences as minor design differences and concludes that the differences will not impact lisdexamfetamine use. We do not believe that these differences will impact critical task performance; thus, these differences do not warrant additional data from an HF validation study at this time. • The numerical graduation markings on the lisdexamfetamine oral syringe are oriented upside down when the tip is facing upwards given that In IFU Step (b) (4) users are instructed, "*With the tip of the oral dosing syringe in place in the adapter, hold the Tradename bottle with 1 hand and turn the bottle upside down.*" See the snapshot of the associated IFU (b) (4) below. This may cause confusion when reading the numbers and lead to wrong dose medication errors. Thus, we provide the Applicant our recommendations in section 3. These changes can be implemented without submitting additional HF validation testing data for Agency review.

Consideration	Yes	No	N/A	Discussion of "Other" Design Differences
				(b) (4) [redacted]

In addition, our independent review identified a medication error concern with the proposed toral syringe (b) (4) [redacted] (b) (4) [redacted] (b) (4) [redacted]. Thus, we recommend the Applicant revise the oral syringe (b) (4) [redacted] See section 3 for our recommendation.

We defer the review of the acceptability of any device specifications to the Office of Pharmaceutical Quality (OPQ).

2.2.2 COMPARATIVE TASK ANALYSES

Consideration	Yes	No	N/A	Discussion of "Other" Task Differences
New, differing, or unique tasks identified?	☒	☐		Applicant Identified: • Lisdexamfetamine is a solution that does not require users to shake the bottle before administration, whereas Onyda XR is a suspension that requires users to shake the bottle for at least 10 seconds before administration. • Lisdexamfetamine does not need to be protected from light, whereas Onyda XR must be protected from light. • Lisdexamfetamine should be disposed of within (b) (4) [redacted] after opening the bottle, whereas Onyda XR should be disposed of within 60 days of opening the bottle.

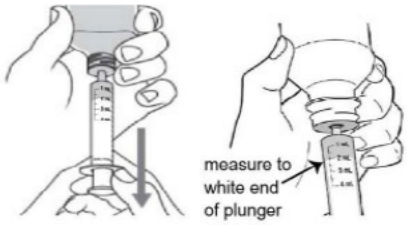
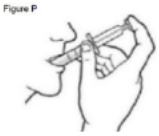
Consideration	Yes	No	N/A	Discussion of "Other" Task Differences
				DMEPA identified: Lisdexamfetamine should be taken in the morning, whereas Onyda XR should be taken at bedtime.
Are the identified tasks likely to negatively impact users' ability to complete the critical tasks needed to use this product safely and effectively as compared to Onyda XR?	☐	☒	☐	• The Onyda XR shake bottle and protect from light tasks are different from lisdexamfetamine; however, these differences do not impact the users' critical task performance; thus, these differences do not warrant additional data from an HF validation study at this time. • The disposal dates between lisdexamfetamine and Onyda XR are different but the product labeling for both products clearly indicate the dispose by day and include a space on the carton for users to list the bottle opened date to track disposal. This difference does not impact the users' critical task performance; thus, additional data from an HF validation study is not warranted. • The difference in the recommended time of day for administration between lisdexamfetamine and Onyda XR is clearly communicated in the product labeling for both products. This difference does not impact the users' critical task performance; thus, additional data from an HF validation study is not warranted.

2.2.3 LABELING COMPARISON

the Applicant's labeling comparison considered the Instructions for Use (IFU), container labels, and carton labeling.

Consideration	Yes	No	N/A	Discussion of "Other" Labeling Differences
Are there "other" design differences	☒	☐		Applicant and DMEPA Identified: Labeling differences corresponding to the physical and

Consideration	Yes	No	N/A	Discussion of "Other" Labeling Differences
labeling differences identified?				task differences described in sections 2.2.1 and 2.2.2 driven by product characteristics. DMEPA Identified: • Both the lisdexamfetamine and Onyda IFUs Step (b) (4) instruct users to "*Pull the plunger down until the white end of the plunger reaches the number of mL you need for the prescribed dose*." However, the relevant lisdexamfetamine IFU figure (b) (4) (b) (4). The Onyda IFU relevant image (Figure K image on the right side), on the other hand, includes an arrow pointing to the white end of the plunger, rather than the plunger rod, which is where users would be expected to measure their dose. • Additionally, the aforementioned lisdexamfetamine IFU (b) (4) (b) (4) (b) (4). However, the Onyda IFU Figure K on the right side focuses on the relevant part of the oral syringe. (b) (4)

Consideration	Yes	No	N/A	Discussion of "Other" Labeling Differences
				Onyda IFU Figure K  • The lisdexamfetamine IFU Step (b) (4) states "*Close the mouth tightly around the oral dosing syringe and slowly push the plunger all the way down to give the TRADENAME dose* (b) (4) (b) (4). The Onyda XR IFU also includes the instruction to close the mouth around the dosing syringe and the associated image depicts a closed mouth. See below. (b) (4) **Onyda IFU** 
Are the identified differences likely to negatively impact users' ability to complete the critical tasks needed to use this product safely and effectively as compared to Onyda XR?	☐	☒	☐	• IFU text and images should align. Mislabeling (b) (4) (b) (4) (b) (4) may cause confusion when measuring the dose and lead to wrong dose medication errors. Thus, we provide the Applicant recommendations in section 3. These changes can be implemented without submitting additional HF validation testing data for Agency review.

Consideration	Yes	No	N/A	Discussion of "Other" Labeling Differences
				• Additionally, in the lisdexamfetamine IFU (b) (4) (b) (4) (b) (4) may cause users confusion when measuring the dose and lead to wrong dose medication errors. Thus, we provide the Applicant recommendations in section 3. These changes can be implemented without submitting additional HF validation testing data for Agency review.

As a general matter, differences in wording, formatting, graphics/illustrations, and location of information have the potential to impact the performance of critical tasks. However, from a medication error perspective, we do not think the differences identified warrant data from a human factors (HF) validation study.

We note labeling will be further reviewed under the marketing application submission.

3 LABELS AND LABELING

Table 3 below includes the identified medication error issues with the submitted product IFU and oral dosing syringe, our rationale for concern, and our proposed recommendations to minimize the risk for medication error.

Table 3. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Instructions for Use (IFU)			
1.	(b) (4) Additionally, you included (b) (4) (b) (4)	IFU text and images should align. Mislabeling (b) (4) may cause confusion when measuring and lead to wrong dose medication errors. Additionally, (b) (4) (b) (4)	Correct this image by moving (b) (4) (b) (4) where users would be expected to read to measure their dose. Additionally, consider, zooming in further on the oral syringe image to ensure it is focused on the relevant part of the oral syringe (b) (4)

Table 3. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
	(b) (4)	(b) (4) may cause users confusion when measuring the dose and lead to wrong dose medication errors.	(b) (4) and surrounding graduation marks), similar to Figure K in the Onyda XR IFU.
2.	The lisdexamfetamine IFU Step (b) (4) states *"Close the mouth tightly around the oral dosing syringe and slowly push the plunger all the way down to give the TRADENAME dose* (b) (4) *";* (b) (4)	IFU text and images should align. Depicting the (b) (4) may cause confusion with the task of "Taking the dose of Tradename" and lead to administration medication errors.	Revise the lisdexamfetamine (b) (4) (b) (4) to align with the IFU text.
Oral dosing syringe			
1.	The numerical graduation markings on the lisdexamfetamine oral syringe are oriented upside down when the tip is facing upwards, whereas the numerical graduation markings on the Onyda XR oral syringe are oriented right side up when the tip is facing upwards.	In IFU Step (b) (4) users are instructed, *"With the tip of the oral dosing syringe in place in the adapter, hold the Tradename bottle with 1 hand and turn the bottle upside down."* The numerical graduation markings appear upside down in that orientation, which may cause confusion when reading the numbers and lead to wrong dose medication errors.	Revise the oral syringe to include the numbers as right-side up on the oral syringe when the tip is facing upwards. Additionally, revise the relevant parts of the proposed product labeling accordingly.

Table 3. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
2.	The lisdexamfetamine oral syringe includes numerical graduation (b) (4) (b) (4) we note the recommended maximum recommended dose of lisdexamfetamine is 7 mL per day.	(b) (4) (b) (4) Because lisdexamfetamine is a schedule II-controlled substance, we are concerned that the presence of numerical graduation markings (b) (4) (b) (4) may contribute to wrong dose medication errors (b) (4) .	Revise the oral syringe to (b) (4) include numerical graduation markings up to the maximum dose of lisdexamfetamine, 7 mL. Additionally, revise the relevant parts of the proposed product labeling accordingly.

4 CONCLUSION

Our review of the use-related risk analysis and comparative analyses did not identify any new, differing, or unique risks for the proposed lisdexamfetamine product as compared to Onyda XR oral suspension. As such, we agree with the Applicant's justification for not submitting human factors (HF) validation study results as part of their marketing application. We have no human HF recommendations for this marketing application.

However, our evaluation of the proposed label and labeling did identify areas of vulnerability that may lead to medication errors. Above, we have provided recommendations in Table 3. We ask that the Division convey Table 3 in its entirety to the Applicant so that recommendations are implemented for this NDA 219847. These changes can be implemented without submitting additional HF validation testing results for Agency review.

5 RECOMMENDATIONS FOR AZURITY PHARMACEUTICALS

Based on our review of the use-related risk analysis and comparative analyses, we have determined that you do not need to submit human factors (HF) validation study results to support your marketing application. However, our evaluation of your proposed label and labeling identified areas of vulnerability that may lead to medication errors. We have provided

our recommendations in Table 3. We have determined that these changes can be implemented without submitting HF validation data for Agency review.

APPENDICES: MATERIALS CONSIDERED FOR THIS REVIEW

APPENDIX A. USE-RELATED RISK ANALYSIS AND COMPARATIVE ANALYSES

The use-related risk analysis (URRA) for lisdexamfetamine submitted on November 6, 2024 can be accessible in EDR via: \\CDSESUB1\EVSPROD\nda219847\0004\m5\53-clin-stud-rep\535-rep-effic-safety-stud\adhd\5354-other-stud-rep\123\study-report-5354-lisdex-urra.pdf

The comparative analyses for lisdexamfetamine submitted on November 6, 2024 can be accessible in EDR via: \\CDSESUB1\EVSPROD\nda219847\0004\m5\53-clin-stud-rep\535-rep-effic-safety-stud\adhd\5354-other-stud-rep\123\study-report-5354-comp-threshold-anlys.pdf

APPENDIX B. INFORMATION REQUESTS ISSUED DURING THE REVIEW

On October 16, 2024 we issued an Information Request (IR) to request the URRA, IFU, any risk controls for the use issues observed in the human factors study, and comparative analyses. On November 6, 2024, the Applicant provided their response that can be accessed in EDR via:

- Applicant's IR response: \\CDSESUB1\EVSPROD\nda219847\0004\m1\us\annexure-2-hf-ir-reponse.pdf
- Updated instructions for use (see Prescribing Information): \\CDSESUB1\EVSPROD\nda219847\0004\m1\us\1-14-1-3-uspi-clean-copy.pdf
- Comparative analyses: \\CDSESUB1\EVSPROD\nda219847\0004\m5\53-clin-stud-rep\535-rep-effic-safety-stud\adhd\5354-other-stud-rep\123\study-report-5354-comp-threshold-anlys.pdf
- URRA: \\CDSESUB1\EVSPROD\nda219847\0004\m5\53-clin-stud-rep\535-rep-effic-safety-stud\adhd\5354-other-stud-rep\123\study-report-5354-lisdex-urra.pdf

APPENDIX C. PRODUCT SAMPLES, LABELS, AND LABELING

C.1 Product Samples

The product samples were submitted for our review, and we provide recommendations for improvement in the Identified Issues and Recommendations table above.

C.2 List of Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[3] along with postmarket medication error experiences with similar products, we reviewed the following lisdexamfetamine labeling submitted by the Applicant on November 6, 2024.

Instructions for use (image now shown, see Prescribing Information): \\CDSESUB1\EVSPROD\nda219847\0004\m1\us\1-14-1-3-uspi-clean-copy.pdf

[3] Institute for Healthcare Improvement (IHI). Failure Modes and Effects Analysis. Boston. IHI:2004.

1 Page(s) of Draft Labeling has been Withheld in Full as b4 (CCI/TS) immediately following this page

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NEHA KUMAR
05/14/2025 12:44:46 PM

MATTHEW J BARLOW
05/14/2025 12:54:11 PM

ARIANE O CONRAD
05/14/2025 01:09:22 PM

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 11/29/2024

TO: Division of Psychiatry (DP)
Office of Neuroscience (ON)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct on-site inspections**

RE: NDA 219847

The Office of Study Integrity and Surveillance (OSIS) determined that inspections are not needed for the sites listed below. The rationale for this decision is noted below.

Rationale

BioPharma Services, Inc.: The Office of Inspections and Investigations (OII) conducted an inspection for the clinical site in (b) (4). The inspection was conducted under the following submission: ANDA NON-RESPONSIVE.

The following items were discussed with the site:

- NON-RESPONSIVE

After review of the discussion items, OSIS concluded that data from the reviewed studies were reliable.

Alpha Laboratories, Inc.: Although OSIS has no inspection history for this site, an inspection of the clinical site is not supportable because there were no subject randomized at the site.

(b) (4)**.:** OSIS conducted an inspection for the analytical site in (b) (4). The inspection was conducted under the following submissions: NON-RESPONSIVE.

OSIS concluded that data from the reviewed studies were reliable.

Sites

Facility Type	Facility Name	Facility Address
Clinical	BioPharma Services, Inc.	4000 Weston Road, Toronto, Ontario, Canada
Clinical	Alpha Laboratories, Inc.	1262 Don Mills Road, Toronto, Ontario, Canada
Analytical		(b) (4)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

FOLAREMI ADEYEMO
11/29/2024 09:15:21 AM