CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219776Orig1s000

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)

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

Date of This Review:	December 1, 2025
Requesting Office or Division:	Division of Pulmonology, Allergy, and Critical Care (DPACC)
Application Type and Number:	NDA 219776
Product Name, Dosage Form, and Strength:	Orladeyo (berotralstat) Oral pellets, (b) (4) mg, 96 mg, 108 mg, and 132 mg
Applicant Name:	BioCryst Pharmaceuticals, Inc. (BioCryst)
FDA Received Date:	November 26, 2025
TTT ID #:	2025-13668-1
DMEPA 1 Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP

1 PURPOSE OF MEMORANDUM

BioCryst Pharmaceuticals, Inc. submitted revised container labels and carton labeling received on November 26, 2025 for Orladeyo. The Division of Pulmonology, Allergy, and Critical Care (DPACC) requested that we review the revised container labels and carton labeling for Orladeyo (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

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

[a] Owens L. Label and Labeling Review for Orladeyo (NDA 219776). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2025 MAY 22. TTT ID: 2025-13668.

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/s/

LISSA C PRINGLE-OWENS
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DAMON A BIRKEMEIER
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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:	November 18, 2025
To:	Linda Ebonine, PA-C Senior Regulatory Health Project Manager **Division of Pulmonology, Allergy, and Critical Care (DPACC)**
Through:	Nyedra Booker, PharmD, MPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
From:	Lonice Carter, MS, RN, CNL, NHDP-BC Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Quynh-Nhu Capasso, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	Orladeyo (berotralstat)
Dosage Form and Route:	oral granules
Application Type/Number:	NDA 219776
Applicant:	BioCryst Pharmaceuticals, Inc.

1 INTRODUCTION

On March 12, 2025, BioCryst Pharmaceuticals, Inc. submitted for the Agency's review an original New Drug Application (NDA) 219776 for Orladeyo (berotralstat) oral granules. This NDA proposes to extend the approved indication of NDA 214094 Orladeyo (berotralstat) to include patients 2 to < 12 years of age with hereditary angioedema (HAE). Per the Applicant's cover letter, this application also provides information on oral granules as an age-appropriate formulation of berotralstat.

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 Pulmonology, Allergy, and Critical Care (DPACC) on March 28, 2025, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for Orladeyo (berotralstat) oral granules.

2 MATERIAL REVIEWED

- Draft Orladeyo (berotralstat) PPI received on March 12, 2025, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on November 7, 2025.
- Draft Orladeyo (berotralstat) Prescribing Information (PI) received on March 12, 2025, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on November 7, 2025.

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.

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.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the PI
- removed unnecessary or redundant information
- ensured that the PPI is free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the PPI meets the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)

4 CONCLUSIONS

The PPI is 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 PPI 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 PPI.

Please let us know if you have any questions.

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/s/

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

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

Memorandum

Date: November 19, 2025

To: Linda Ebonine, Senior Regulatory Health Project Manager
Division of Pulmonology and Critical Care (DPACC)

From: Quynh-Nhu Capasso, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Adewale Adeleye, Team Leader, OPDP

Subject: OPDP Labeling Comments for ORLADEYO (berotralstat) capsules, for oral use; ORLADEYO (berotralstat) oral pellets

NDA: 219776

Background:
In response to DPACC's consult request dated March 28, 2025, OPDP has reviewed the proposed Prescribing Information (PI), Patient Package Insert (PPI), and carton and container labeling for the original NDA submission for ORLADEYO (berotralstat) capsules, for oral use; ORLADEYO (berotralstat) oral pellets.

PI/PPI:
OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on November 7, 2025, and our comments are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review was completed for the proposed PPI, and comments were sent under separate cover.

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 March 12, 2025, and our comments are provided below.

Thank you for your consult. If you have any questions, please contact Quynh-Nhu Capasso at quynh-nhu.capasso@fda.hhs.gov

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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: July 3, 2025

TO: Sally Seymour, M.D.
Director
Division of Pulmonology, Allergy, and Critical Care (DPACC)
Office of Immunology and Inflammation (OII)
Office of New Drugs (OND)

FROM: Yiyue Zhang, Ph.D.
Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance (OSIS)

THROUGH: Arindam Dasgupta, Ph.D.
Acting Director
DNDSI, OSIS

SUBJECT: Review of Analytical Remote Regulatory Assessment (RRA) (b) (4)

Remote Regulatory Assessment (RRA) Summary

Per the request of OND/OII/DPACC, OSIS conducted an RRA of analytical portion of **Study BCX7353-304** [NDA 219776, Orladeyo (Berotralstat) oral granules] conducted (b) (4)

I did not observe any objectional conditions at the conclusion of the RRA. Based on the RRA findings and OSIS evaluation, I conclude that there are no identified concerns regarding data reliability of **Study BCX7353-304** for the review division consideration.

Reviewed Study

NDA 219776

Study Number: BCX7353-304

Study Title: "*A Phase 3 Study to Evaluate the Safety and Pharmacokinetics of Berotralstat Prophylaxis in*

Children with Hereditary Angioedema who are 2 to <12 Years of Age"

Dates of Sample Analysis: March 23, 2023 - September 25, 2024

Bioanalysis Methodology: LC-MS/MS

Analytical Site: (b) (4)

I, OSIS scientist Yiyue Zhang conducted an RRA (b) (4)

Previous Inspection and RRA

The site has no previous FDA BIMO inspection history. The previous FDA BIMO Remote Record Review (RRR) was conducted by OSIS in (b) (4) covering PK and immunogenicity studies using ligand-binding assay (LBA) methodology. At the RRR closeout, objectionable conditions were observed on: (b) (4) I verified the corrective and preventive actions during the current RRA and they appeared to be adequate.

Current RRA

The current RRA included a thorough examination of study records of method validation and sample analysis, standard operating procedures (SOPs), facility, training of study personnel, calibration and maintenance records and audit trails of instruments used in the reviewed study, as well as interviews with the site's management and staff.

RRA Findings

At the conclusion of the current RRA, I did not observe any objectionable conditions.

Additional Findings

During the RRA, I also found that three samples were received after completion of sample analysis of Study BCX7353-304 as

stated in the study report. These samples were not analyzed and they were disposed per the sponsor's request (**Attachment 1**). I identified the samples during the RRA as listed in table below.

Subject ID	Sample ID	Visit	Sample Receipt Date
(b) (4)			

OCP Reviewer's Concerns

The OCP reviewer identified several reporting discrepancies between the submitted clinical study reports versus adpc.xpt and adsl.xpt for subjects who received modified doses of Berotralstat. Dose was modified for some subjects according to weight change, safety and/or PK findings under Protocol version 3.0 as reported in the study report.

During the RRA, I reviewed the bioanalytical source documents, including sample receipt and tracking records, bioanalytical laboratory worksheets, raw chromatograms and audit trails, Watson LIMS records, correspondence with the sponsor, and relevant Note-to-Files (**Attachments 2 and 3**). Each subject sample was assigned a unique ID number, and the corresponding collection timepoint was based on the clinical manifest and documented in Watson LIMS accordingly.

Although the sponsor's reporting discrepancies were noted, I did not observe any issue with (b) (4) bioanalytical conduct and reporting of concentration data. Because the sample names were generated based on the clinical manifest, it is likely that the sample names as provided by the clinical site did not accurately reflect the corresponding dose adjustments. Therefore, I recommend the review division to contact the sponsor for clarification regarding the reporting discrepancies between the submitted clinical study reports versus adpc.xpt and adsl.xpt data in relation to subjects that received adjusted doses.

Yiyue Zhang, Ph.D.
Senior Staff Fellow

(b) (4)

Attachments:

Attachment 1. (b) (4)

Attachment 2.

Attachment 3.

Draft: YZ 06/13/2025, 06/18/2025, 06/20/2025, 06/30/2025
Edit: GB 06/16/2025, 06/18/2025, 06/24/2025, 07/03/2025

OSIS File#: (b) (4)
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/s/

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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)

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Date of This Review:	May 22, 2025
Requesting Office or Division:	Division of Pulmonology, Allergy, and Critical Care (DPACC)
Application Type and Number:	NDA 219776
Product Name, Dosage Form, and Strength:	Orladeyo (berotralstat) Oral granules, (b) (4) mg, 96 mg, 108 mg, and 132 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant Name:	BioCryst Pharmaceuticals, Inc. (BioCryst)
FDA Received Date:	March 12, 2025
TTT ID #:	2025-13668
DMEPA 1 Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP

1 INTRODUCTION

As part of the approval process for Orladeyo (berotralstat) Oral granules, the Division of Pulmonology, Allergy, and Critical Care (DPACC) requested that we review the proposed Orladeyo Prescribing Information (PI), Patient Information, container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 REGULATORY HISTORY

On December 3, 2020, Orladeyo was approved under NDA 214094 as a capsule for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older, in 110 mg and 150 mg strengths.

On March 12, 2025, BioCryst submitted the proposed labels and labeling for Orladeyo (berotralstat) under NDA 219776 as (b) (4) mg, 96 mg, 108 mg, and 132 mg unit-dose packets of oral granules for the expanded use of prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 2 years and older.

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
Labels and Labeling	B

3 CONCLUSION

We evaluated the proposed Orladeyo Prescribing Information (PI) and Patient Information and determined that they are acceptable from a medication error perspective.

However, the proposed Orladeyo container labels and carton labeling 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 recommendations to minimize the risk for medication error for BioCryst Pharmaceuticals, Inc. in Section 4.

4 RECOMMENDATIONS FOR BIOCRYST PHARMACEUTICALS, INC.

Table 2. Identified Issues and Recommendations for BioCryst Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Labels and Carton Labeling			
1.	It is not immediately clear that the designated strengths are per single unit (packet).	Failure to clearly express the product strength in XX milligram per single unit (packet) may lead to wrong dose error.	We recommend revising the strength statement from "XX mg" to state "XX mg per packet" to make it clear that the designated strength is per unit so there is no confusion as to how much product is contained in a single unit as compared to the total contents of the entire blister card. See Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (May 2022).
Foil Container Labels			
1.	The linear barcode is missing on the foil container label.	The drug barcode is often used as an additional verification during the medication use process; therefore, it is an important safety feature that should be part of the label and is a requirement per 21 CFR 201.25(c)(2).	Add the product's linear barcode to each individual container label (foil) in accordance with 21 CFR 201.25(c)(2). The bar code should be placed in a conspicuous location where it will not be difficult to read because of distorted text. Additionally, the barcode should be placed in an area where it will not be damaged because it appears at the point of label separation (e.g., perforation).
Wallet Labels			
1.	As presented the net quantity statement on	The presentation containing both "seven" and "(7)"	We recommend revising the statement on the wallet from

Table 2. Identified Issues and Recommendations for BioCryst Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
	the wallet is expressed as "Contains seven (7) XX mg packets".	adjacent to the strength may cause confusion. Additionally, the parenthesis may be overlooked resulting in an added "7" to the beginning of the strength.	"Contains seven (7) XX mg packet" to "Contains 7 unit dose packets each containing XX mg".
2.	The net quantity statement located on the wallet is in close proximity to the product strength.	From post-marketing experience, the risk of numerical confusion between the strength and net quantity increases when the net quantity statement is located in close proximity to the strength statement. Product selection or dosing errors can occur if the net quantity statement is mistaken for the product strength, leading to [under- or over-dosing].	We recommend relocating the net quantity statement away from and less prominently than the product strength. For example, consider relocating the net quantity statement to the bottom left or bottom right of the principal display panel of the wallet label.
3.	The placeholder for the lot number is missing.	Lot number statement is required on the immediate container AND carton labeling when there is sufficient space per 21 CFR 201.10(i)(1).	Add the placeholder for the lot number on the wallet in accordance 21 CFR 201.10(i)(1).
4.	The placeholder for the expiration date is missing.	The label of an official drug product shall bear an expiration date per USP General Chapter <7>.	Add the placeholder for the expiration date on the wallet in accordance with USP General Chapter <7>. The USP Chapter <7> Labeling requires the expiration date to appear on the immediate container and all other packaging. When all-numeric dates are used, they must be formatted using

Table 2. Identified Issues and Recommendations for BioCryst Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			the year, the month, and, if applicable, the day, separated by hyphens or forward slashes in one of the following formats: YYYY-MM-DD or YYYY-MM. When alphanumeric dates are used, months must be displayed using at least three letters in one of the following formats: YYYY-MMM-DD or YYYY-MMM. We recommend you ensure that there are no other numbers located in close proximity to the expiration date. To minimize confusion and reduce the risk for deteriorated drug medication errors, identify the expiration date format you intend to use.
5.	The route of administration statement (b) (4) is present on the wallet.	This statement is not required information. The route of administration is only required if the product is not for oral use per 21 CFR 201.100(b)(3).	Consider deleting the statement (b) (4).
6.	As presented in the instructional information on the inside of the wallet labels, in the image under "Step 1: Prepare", the location of the 'cut-line' is unclear.	Lack of clarity.	We recommend updating the figure to more clearly represent the location of the 'cut-line' .
Carton Labeling			
1.	The product identifier is missing.	In June 2021, FDA finalized the Guidance for Industry on product identifiers required under the Drug Supply Chain Security Act	We recommend that you review the guidance to determine if the product identifier requirements apply to your product's labeling.

Table 2. Identified Issues and Recommendations for BioCryst Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
		(DSCSA). The Act requires manufacturers and re-packagers to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in(to) commerce. The product identifier includes the NDC, serial number, lot number, and expiration date in both a human-readable form and machine-readable (2D data matrix barcode) format.	See Guidance for Industry: *Product Identifiers under the Drug Supply Chain Security Act - Questions and Answers (June 2021)*. If you determine that the product identifier requirements apply to your product's labeling, we request you add a place holder to the carton labeling.
2.	The route of administration statement (b) (4) is present on the carton labeling.	This statement is not required information. The route of administration is only required if the product is not for oral use per 21 CFR 201.100(b)(3).	Consider deleting the statement (b) (4).
3.	The placeholder for the expiration date is missing.	The label of an official drug product shall bear an expiration date per USP General Chapter <7>.	Add the placeholder for the expiration date on the carton labeling in accordance with USP General Chapter <7>. The USP Chapter <7> Labeling requires the expiration date to appear on the immediate container and all other packaging. When all-numeric dates are used, they must be formatted using the year, the month, and, if applicable, the day, separated by hyphens or forward slashes in one of the following formats: YYYY-MM-DD or YYYY-MM. When alphanumeric dates are used, months must be displayed

Table 2. Identified Issues and Recommendations for BioCryst Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			using at least three letters in one of the following formats: YYYY-MMM-DD or YYYY-MMM. We recommend you ensure that there are no other numbers located in close proximity to the expiration date. To minimize confusion and reduce the risk for deteriorated drug medication errors, identify the expiration date format you intend to use.
4.	The placeholder for the lot number is missing.	Lot number statement is required on the immediate container AND carton labeling when there is sufficient space per 21 CFR 201.10(i)(1).	Add the placeholder for the lot number on the carton labeling in accordance 21 CFR 201.10(i)(1).

APPENDICES: MATERIALS CONSIDERED FOR THIS REVIEW

APPENDIX A. RELEVANT PRODUCT INFORMATION

Table 3 presents relevant product information for Orladeyo oral granules and Orladeyo capsules received on March 12, 2025 from BioCryst Pharmaceuticals, Inc.

Table 3. Relevant Product Information for Orladeyo (NDA 219776) and Orladeyo (NDA 214094)		
Proprietary name:	Orladeyo *(Proposed)*	Orladeyo
Application Number:	NDA 219776	NDA 214094
Intended pronunciation:	or-luh-DAY-oh	or-luh-DAY-oh
Initial Approval Date	N/A	December 3, 2020
Active ingredient:	berotralstat	berotralstat
Indication:	Prophylaxis to prevent attacks of HAE in pediatric patients 2 years of age to less than 12 years of age.	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older
Dosage Form:	Oral granules	Capsules
Strength:	(b) (4) mg, 96 mg, 108 mg, and 132 mg	110 mg and 150 mg
Route of administration:	Oral	Oral
Dose and frequency:	(b) (4)	Recommended dosage in patients 12 years and older: 150 mg (one capsule) taken orally once daily with food. Decrease the dose to 110 mg orally once daily in patients experiencing gastrointestinal adverse reactions or in patients with moderate or severe hepatic impairment

Table 3. Relevant Product Information for Orladeyo (NDA 219776) and Orladeyo (NDA 214094)		
How Supplied:	• Supplied as small, white to off-white, film-coated granules. • A 28-day supply of ORLADEYO oral granules is provided in a carton containing 4 wallets, each containing 7 child-resistant unit-dose packets. NDC 72769-XXX-XX ((b) (4) mg), NDC 72769-XXX-XX (96 mg), NDC 72769-XXX-XX (108 mg), and NDC 72769-XXX-XX (132 mg).	• 150 mg: a white opaque body with a black imprint “150” and a light blue opaque cap with a black imprint “BCX”. • 110 mg: light blue opaque capsules with a white imprint “110” on body and a white imprint “BCX” on cap. • A 28-day supply of ORLADEYO is provided in a carton containing 4 child-resistant shellpacks, each containing a 7-capsule blister card. NDC 72769 101 01 (150 mg) and NDC 72769 102 01 (110 mg).
Storage:	20°C to 25°C (68°F to 77°F); Excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].	20°C to 25°C (68°F to 77°F); Excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Container Closure	(b) (4)	

APPENDIX B. LABELS AND LABELING

B.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[a] along with postmarket medication error data, we reviewed the following Orladeyo labels and labeling submitted by BioCryst Pharmaceuticals, Inc.

- Prescribing Information received on March 12, 2025, available from \\CDSESUB1\EVSPROD\nda219776\0001\m1\us\m1-14-1-2-annotated-draft-labeling-text.pdf
- Patient Package Insert received on March 12, 2025, available from \\CDSESUB1\EVSPROD\nda219776\0001\m1\us\m1-14-1-2-annotated-draft-labeling-text.pdf
- Container labels received on March 12, 2025
- Carton labeling received on March 12, 2025

B.2 Container Labels and Carton Labeling Images

Container Labels:

Foil

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

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/s/

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