CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219122Orig1s000

OTHER REVIEW(S)

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:	January 2, 2025
To:	A. Christine Wright, RQAP-GLP Regulatory Project Manager **Division of Diabetes, Lipid Disorders, and Obesity (DDLO)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** 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)** Tierra Butler, PharmD Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Medication Guide (MG)
Drug Name (established name):	BRYNOVIN (sitagliptin)
Dosage Form and Route:	Oral Solution
Application Type/Number:	NDA 219122
Applicant:	Azurity Pharmaceuticals, Inc.

1 INTRODUCTION

On November 18, 2024, Azurity Pharmaceuticals, Inc. submitted for the Agency's review a Class 1 Resubmission for original New Drug Application (NDA) 219122 BRYNOVIN (sitagliptin) Oral Solution, in response to the Complete Response Letter issued by the Agency on November 4, 2024. This submission is a 505(b)(2) NDA and the Reference Listed Drug is JANUVIA (sitagliptin) NDA 021995. The purpose of this NDA is to propose the following indication for BRYNOVIN (sitagliptin): as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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 Diabetes, Lipid Disorders, and Obesity (DDLO) on December 11, 2024 for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG) for BRYNOVIN (sitagliptin) Oral Solution.

2 MATERIAL REVIEWED

- Draft BRYNOVIN (sitagliptin) MG received on November 18, 2024, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on December 12, 2024.
- Draft BRYNOVIN (sitagliptin) Prescribing Information (PI) received on November 18, 2024, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on December 12, 2024.
- Approved JANUVIA (sitagliptin) tablets, for oral use comparator labeling dated December 28, 2023.
- Approved ZITUVIO (sitagliptin) tablets, for oral use comparator labeling dated October 18, 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.

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 document using the Arial font, size 10.

In our collaborative review of the MG we:

- simplified wording and clarified concepts where possible
- ensured that the MG is consistent with the PI
- removed unnecessary or redundant information

- ensured that the MG is 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 MG is consistent with the approved comparator labeling where applicable

4 CONCLUSIONS

The MG 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 MG 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.

Please let us know if you have any questions.

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/s/

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NYEDRA W BOOKER
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LASHAWN M GRIFFITHS
01/02/2025 01:50:58 PM

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

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

Memorandum

Date: January 2, 2025

To: Christine Wright, Regulatory Project Manager, Division of Diabetes, Lipid Disorders, and Obesity (DDLO)

Lauren Wood Heickman, Clinical Reviewer, DDLO

Melinda Wilson, Associate Director for Labeling, DDLO

From: Tierra Butler, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sapna Shah, Team Leader, OPDP

Subject: OPDP Labeling Comments for BRYNOVIN (sitagliptin) Oral Solution

NDA: 219122

Background:
In response to DDLO's consult request dated December 11, 2024, OPDP has reviewed the proposed Prescribing Information (PI), Medication Guide, and carton and container labeling for the original NDA submission for BRYNOVIN.

PI/Medication Guide:
OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on December 12, 2024, 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 comments will be sent under separate cover.

Carton and Container Labeling:
OPDP's review of the proposed carton and container labeling is based on the draft labeling emailed to OPDP on December 12, 2024, and we do not have any comments at this time.

Thank you for your consult. If you have any questions, please contact Tierra Butler at (301) 796-1368 or tierra.butler@fda.hhs.gov.

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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:	December 16, 2024
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 219122
Product Name, Dosage Form, and Strength:	Brynovin (sitagliptin) oral solution, 25 mg/mL
Applicant Name:	Azurity Pharmaceuticals, Inc.
FDA Received Date:	November 18, 2024
TTT ID #:	2024-7822-1
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

1 PURPOSE OF MEMORANDUM

Azurity Pharmaceuticals, Inc. submitted revised container label and carton labeling received on November 18, 2024 for Brynovin. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the revised container label and carton labeling for Brynovin (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 REGULATORY HISTORY

Azurity Pharmaceuticals, Inc. previously submitted NDA 219122 on January 4, 2024, which received a Complete Response on November 04, 2024 due to issues with facility inspections.[b]

Thus, Azurity Pharmaceuticals, Inc. submitted a Class 2 Resubmission on November 18, 2024.[c]

3 DISCUSSION

The established name was updated from "sitagliptin hydrochloride" to "sitagliptin" in response to previous comments from our OPQ colleagues. This change has been updated on the container label, carton labeling, and other labeling materials.

4 CONCLUSION

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

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[a] Patel, V. Label and Labeling Review for Brynovin (NDA 219122). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Mar 15. TTT ID: 2024-7822.

[b] Salartash, S on behalf of Patrick Archdeacon. Complete Response for NDA 219122. Silver Spring (MD): FDA, CDER, OND, Division of Diabetes, Lipid Disorders, and Obesity (DDLO) (US); 2024 Nov 04.

[c] Resubmission: Response to Complete Response Letter for sitagliptin hydrochloride NDA 219122. Woburn (MA): Azurity Pharmaceuticals, Inc.; 2024 Nov 18. Available from: \\CDSESUB1\EVSPROD\nda219122\0020\m1\us\cover-letter-seq-0020.pdf.

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/s/

VRAJ K PATEL
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DAMON A BIRKEMEIER
12/16/2024 09:27:41 AM

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

REVIEW DEFERRAL MEMORANDUM

Date:	October 8, 2024
To:	Shiva Salartash Regulatory Project Manager **Division of Diabetes, Lipid Disorders, and Obesity (DDLO)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Marcia Williams, PhD Team Leader, Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Mary Carroll, BSN, RN Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
Subject:	Review Deferred: Medication Guide (MG)
Drug Name (established name):	TRADENAME (sitagliptin hydrochloride)
Dosage Form and Route:	oral solution
Application Type/Number:	NDA 219122
Applicant:	Azurity Pharmaceuticals, Inc.

1 INTRODUCTION

On January 4, 2024, Azurity Pharmaceuticals submitted for the Agency's review an Original New Drug Application (NDA) 219122 for TRADENAME (sitagliptin hydrochloride) oral solution. The reference listed drug is JANUVIA (sitagliptin). The purpose of this NDA is to propose the use of TRADENAME (sitagliptin hydrochloride) oral solution as a formulation that address the challenges with the dosing of solid oral dosage forms of sitagliptin in patients with difficulty swallowing a tablet formulation and was developed under pIND 155653 in consultation with the Agency.

On February 8, 2024, the **Division of Diabetes, Lipid Disorders, and Obesity (DDLO)** requested that the Division of Medical Policy Programs (DMPP) review the Applicant's proposed Medication Guide (MG) for TRADENAME (sitagliptin).

This memorandum documents the DMPP review deferral of the Applicant's proposed Medication Guide (MG) for TRADENAME (sitagliptin).

2 CONCLUSIONS

Due to outstanding facility deficiencies, DDLO plans to issue a Complete Response (CR) letter.

Therefore, DMPP defers comment on the Applicant's patient labeling at this time. A final review will be performed after the Applicant submits a complete response to the Complete Response (CR) letter. Please send us a new consult request at such time.

Please notify us if you have any questions.

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/s/

MARY E CARROLL
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MARCIA B WILLIAMS
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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: October 7, 2024

To: Shiva Salartash, Regulatory Project Manager, Division of Diabetes, Lipid Disorders, and Obesity (DDLO)

Lauren Wood Heickman, MD, Clinical Reviewer, DDLO

Melinda Wilson, Associate Director for Labeling, DDLO

From: Tierra Butler, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

CC: Sapna Shah, Team Leader, OPDP

Subject: OPDP Labeling Comments for Brynovin (sitagliptin hydrochloride) oral solution

NDA: 219122

Background:

This memo is in response to DDLO's labeling consult request dated February 08, 2024. OPDP defers comment on the proposed labeling at this time, and requests that DDLO submit a new consult request during the subsequent review cycle. If you have any questions, please contact Tierra Butler at (301) 796-1368 or tierra.butler@fda.hhs.gov.

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/s/

TIERRA N BUTLER
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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: 4/29/2024

TO: Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN)

FROM: Office of Study Integrity and Surveillance (OSIS)

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

RE: NDA 219122

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

Worldwide Clinical Trials, San Antonio: The Office of Regulatory Affairs (ORA) conducted an inspection for the site in September 2022. The inspection was conducted under the following submission: NON-RESPONSIVE

OSIS concluded that data from the reviewed studies were reliable.

(b) (4) OSIS conducted a Remote Regulatory Assessment (RRA) for the site in (b) (4) The RRA was conducted under the following submission: NON-RESPONSIVE

OSIS concluded that data from the reviewed studies were reliable.

Sites

Facility Type	Facility Name	Facility Address
Clinical	Worldwide Clinical Trials (WCT) Early Phase Services, LLC.	2455 Northeast Loop 410, Suite 150, San Antonio, TX
Analytical	(b) (4)	

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FELECIA P HAGOOD
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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:	March 15, 2024
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 219122
Product Name, Dosage Form, and Strength:	Brynovin (sitagliptin HCl) oral solution, 25 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Azurity Pharmaceuticals, Inc.
FDA Received Date:	January 4, 2024
TTT ID #:	2024-7822
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

1 REASON FOR REVIEW

As part of the approval process for Brynovin (sitagliptin HCl) oral solution, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the proposed Brynovin prescribing information (PI), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUD

NDA 219122 is a 505(b)(2) NDA and the listed drug product is Januvia, NDA 021995.

2 MATERIALS REVIEWED

Table 1. Materials Considered for this Label and Labeling Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A
Previous DMEPA Reviews	B
ISMP Newsletters*	C – N/A
FDA Adverse Event Reporting System (FAERS)*	D – N/A
Other	E – N/A
Labels and Labeling	F

N/A=not applicable for this review
*We do not typically search FAERS or ISMP Newsletters for our label and labeling reviews unless we are aware of medication errors through our routine postmarket safety surveillance

3 CONCLUSION AND RECOMMENDATIONS

The proposed PI, 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 in Section 4 for the Division and in Section 5 for Azurity Pharmaceuticals, Inc.

4 RECOMMEDATIONS FOR DIVISION OF DIABETES, LIPID DISORDERS, AND OBESITY (DDLO)

Table 2. Identified Issues and Recommendations for Division of Diabetes, Lipid Disorders, and Obesity (DDLO)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Prescribing Information – General Issues			
1.	The milliliter equivalent for the dose is not right next to the dose [e.g., 100 mg once daily (4 mL)].	Not putting the milliliter equivalent next to the dose can lead to a wrong dose medication error.	We recommend updating the dosing language in the prescribing information so that the milliliter equivalent is next to the dose [e.g., 100 mg (4 mL) once daily].
Full Prescribing Information – Section 16 How Supplied/Storage and Handling			
1.	The total volume of the bottle is not clearly defined.	It is currently unclear what "120 mL" refers to and may lead to a wrong dose medication error or a dispensing error.	We recommend updating "120 mL, NDC 24338-017-01" to read, "One 120 mL bottle, NDC 24338-017-01".

5 RECOMMENDATIONS FOR AZURITY PHARMACEUTICALS, INC.

Table 3. 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 format for expiration date is not defined.	Clearly defining the expiration date will minimize confusion and risk for deteriorated drug medication errors.	Identify the expiration date format you intend to use. FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day. FDA recommends that the expiration date appear in YYYY-MM-DD format if only numerical characters are used or in YYYY-MMM-DD if alphabetical characters are used to represent the month. If there are space limitations on the drug package, the human-readable text may

Table 3. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			include only a year and month, to be expressed as: YYYY-MM if only numerical characters are used or YYYY-MMM if alphabetical characters are used to represent the month. FDA recommends that a hyphen or forward slash be used to separate the portions of the expiration date.
2.	The terminology within the statement of dosage statement (i.e., (b) (4) (b) (4) is inconsistent with the terminology in the Prescribing Information.	To ensure consistency with the terminology in the Prescribing Information.	We recommend revising the statement of dosage statement to read, "Recommended Dosage: See Prescribing Information.
3.	The placement of the graphic at the beginning of the proprietary name looks like the letter 'B' and competes with the legibility of the proprietary name, which may lead to misinterpretation of the proprietary name as BBrynovin or something else.	Placing a logo immediately before the proprietary name can lead to misinterpretation because logos may look like an additional letter in the proprietary name or detract from legibility.	Delete, move, and/or decrease the prominence of the graphic at the beginning of the proprietary name.
4.	The statement, "For Oral Administration Only" is not present on the container label or carton labeling.	To minimize the risk of wrong route of administration errors, the route of administration statement should be on the container label and carton labeling.	We recommend adding the statement, "For Oral Administration Only" to the principal display panel of the carton labeling and the container label.
Carton Labeling			

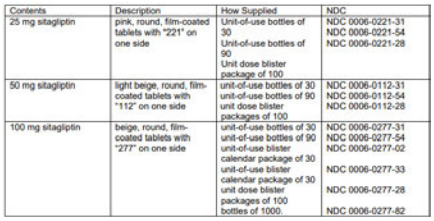
Table 3. Identified Issues and Recommendations for Azurity Pharmaceuticals, Inc. (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
1.	As currently presented, the proprietary name and established name lack prominence on the principal display panel compared to the strength.	The proprietary name and established name should be the most prominent information on the principal display panel.	We recommend increasing the prominence of the proprietary name and established name as compared to the strength. Consider the use of different font type or size, bolding, color, or other means to achieve increased prominence. See Guidance for Industry: Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (May 2022).

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table presents relevant product information for Brynovin that Azurity Pharmaceuticals, Inc. submitted on January 4, 2024, and the listed drug (LD).

Table 4. Relevant Product Information for Listed Drug and Brynovin

Product Name	Januvia[a]	Brynovin
Initial Approval Date	October 16, 2006	N/A
Active Ingredient	Sitagliptin phosphate	Sitagliptin hydrochloride
Indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	
Route of Administration	Oral	
Dosage Form	tablet	Oral solution
Strength	100 mg, 50 mg, 25 mg	25 mg/mL
Dose and Frequency	Take 100 mg once daily. Can be taken with or without food. Dosage Adjustment in Patients with Renal Impairment (2.2) eGFR greater than or equal to 30 mL/min/1.73 m² to less than 45 mL/min/1.73 m²: 50 mg once daily eGFR less than 30 mL/min/1.73 m² (including patients with end stage renal disease [ESRD] on dialysis): 25 mg once daily	Take 100 mg (4 mL) once daily. Can be taken with or without food. **Dosage Adjustment in Patients with Renal Impairment (2.2)** eGFR greater than or equal to 30 mL/min/1.73 m² to less than 45 mL/min/1.73 m²: 50 mg once daily (2 mL) eGFR less than 30 mL/min/1.73 m² (including patients with end stage renal disease [ESRD] on dialysis): 25 mg once daily (1 mL)
How Supplied	 Contents / Description / How Supplied / NDC 25 mg sitagliptin: pink, round, film-coated tablets with "221" on one side; Unit-of-use bottles of 30: NDC 0006-0221-31; Unit-of-use bottles of 90: NDC 0006-0221-54; Unit dose blister package of 100: NDC 0006-0221-28 50 mg sitagliptin: light beige, round, film-coated tablets with "112" on one side; unit-of-use bottles of 30: NDC 0006-0112-31; unit-of-use bottles of 90: NDC 0006-0112-54; unit dose blister packages of 100: NDC 0006-0112-28 100 mg sitagliptin: beige, round, film-coated tablets with "277" on one side; unit-of-use bottles of 30: NDC 0006-0277-31; unit-of-use bottles of 90: NDC 0006-0277-54; unit-of-use blister calendar package of 30: NDC 0006-0277-02; unit-of-use blister calendar package of 30: NDC 0006-0277-33; unit dose blister packages of 100: NDC 0006-0277-28; bottles of 1000: NDC 0006-0277-82	25 mg/mL is supplied as a clear colorless, to nearly colorless aqueous solution in an amber class bottle with a child resistant closure. 120 mL, NDC 24338-017-01
Storage	Store at 20-25°C (68-77°F), excursions permitted to 15-30°C (59-86°F).	Store refrigerated at 2°C to 8°C (36°F to 46°F) [see USP]; Protect from light. Avoid excessive heat and freezing. Discard unused portion 90 days after first opening.

[a] Januvia [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. December 2023. [cited 2024 Feb 06]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/021995Orig1s053lbl.pdf.

APPENDIX B. PREVIOUS DMEPA REVIEWS

On February 6, 2024, we searched for previous DMEPA reviews relevant to this current review using the term “NDA 219122”. Our search identified zero previous reviews.

APPENDIX F. LABELS AND LABELING

F.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[b] along with postmarket medication error experiences with similar products, we reviewed the following Brynovin labels and labeling submitted by Azurity Pharmaceuticals, Inc.

- Container label received on January 4, 2024
- Carton labeling received on January 4, 2024
- Medication Guide received on January 4, 2024, available from \\CDSESUB1\EVSPROD\nda219122\0001\m1\us\1-14-1-3-med-guide.pdf.
- Prescribing Information (Image not shown) received on January 4, 2024, available from \\CDSESUB1\EVSPROD\nda219122\0001\m1\us\1-14-1-3-prescribing-info-label.pdf.

F.2 Label and Labeling Images

Container label

(b) (4)

[redacted]

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

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