CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216778Orig1s000

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:	July 12, 2024
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 216778
Product Name, Dosage Form, and Strength:	Zituvimet XR (sitagliptin and metformin hydrochloride) extended-release tablets, 100 mg/1,000 mg, 50 mg/500 mg, and 50 mg/ 1,000 mg
Applicant Name:	Zydus Pharmaceuticals Inc.
FDA Received Date:	July 12, 2024
TTT ID #:	2023-6512-3
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

1 PURPOSE OF MEMORANDUM

Zydus Pharmaceuticals Inc. submitted revised container labels received on July 12, 2024 for Zituvimet XR. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the revised container labels for Zituvimet XR (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

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

[a] Patel, V. Label and Labeling Review for Zituvimet XR (NDA 216778). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2024 Jul 02. TTT ID: 2023-6512-2.

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VRAJ K PATEL
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DAMON A BIRKEMEIER
07/12/2024 04:27:41 PM

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:	July 9, 2024
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)** Marcia Williams, PhD Team Leader, Patient Labeling **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):	ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release)
Dosage Form and Route:	tablets, for oral use
Application Type/Number:	NDA 216778
Applicant:	Zydus Worldwide DMCC C/O: Zydus Pharmaceuticals (USA) Inc.

1 INTRODUCTION

On September 22, 2023, Zydus Worldwide DMCC C/O: Zydus Pharmaceuticals (USA) Inc. submitted for the Agency's review an original 505(b)(2) New Drug Application (NDA) 216778 for ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use. The reference listed drug is JANUMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use (NDA # 202270). The purpose of this submission is to propose an indication of ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) 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 October 2, 2023, for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG) for ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use.

2 MATERIAL REVIEWED

- Draft ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) MG received on September 22, 2023, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on June 25, 2024.
- Draft ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) Prescribing Information (PI) received on September 22, 2023, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on June 25, 2024.
- Approved JANUMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use comparator labeling dated June 21, 2022.

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 Prescribing Information (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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MARCIA B WILLIAMS
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LASHAWN M GRIFFITHS
07/09/2024 09:21:58 AM

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

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

Memorandum

Date: July 2, 2024

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

Susan Yuditskaya, MD, Clinical Reviewer, DDLO

Melinda Wilson, PharmD, MPH, Associate Director for Labeling, DDLO

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

CC: Sapna Shah, PharmD, Team Leader, OPDP

Subject: OPDP Labeling Comments for ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use

NDA: 216778

Background:
In response to DDLO's consult request dated October 2, 2023, OPDP has reviewed the proposed Prescribing Information (PI), Medication Guide, and carton and container labeling for the original NDA submission for ZITUVIMET XR (sitagliptin and metformin hydrochloride extended-release) tablets, for oral use (Zituvimet XR).

PI/Medication Guide:
OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on June 25, 2024, and our comments are provided below.

A combined OPDP and Division of Medical Policy Programs (DMPP) review will be 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 June 28, 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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TIERRA N BUTLER
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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:	July 02, 2024
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 216778
Product Name, Dosage Form, and Strength:	Zituvimet XR (sitagliptin and metformin hydrochloride) extended-release tablets, 100 mg/1,000 mg, 50 mg/500 mg, and 50 mg/ 1,000 mg
Applicant Name:	Zydus Pharmaceuticals Inc.
FDA Received Date:	June 28, 2024
TTT ID #:	2023-6512-2
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

1 PURPOSE OF MEMORANDUM

Zydus Pharmaceuticals Inc. submitted revised container labels received on June 28, 2024 for Zituvimet XR. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the revised container labels for Zituvimet XR (Appendix A) to determine if they are acceptable from a medication error perspective. The revisions are in response to an information request issued by DDLO on June 25, 2024.

2 CONCLUSION

The container labels are unacceptable 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 3 for Zydus Pharmaceuticals Inc.

3 RECOMMENDATIONS FOR ZYDUS PHARMACEUTICALS INC.

A. Container Labels

1. As currently presented, there is no space for end-users to write the beyond-use date which is the date the opened product must be discarded. Since the product has a different expiration date after opening, the container label should have a designated space and format for end-users to write the beyond-use date to minimize the risk of deteriorated drug medication errors. We recommend including space for end-users to write the beyond-use date on the container label. For example: “Discard after ___/____/____.”

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APPENDIX D. INFORMATION REQUEST

Information Request, sent on June 25, 2024, available from https://darrts.fda.gov/darrts/faces/ViewDocument?documentId=090140af8075138c.

- OND requested adding the following statements:
  - Dispense in original container.
  - Keep Zituvimet XR in the original container to protect it from moisture.
  - Use within 30 days of opening.

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/s/

VRAJ K PATEL
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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)

Date of This Memorandum:	January 25, 2024
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 216778
Product Name, Dosage Form, and Strength:	Zituvimet XR (sitagliptin and metformin hydrochloride) Extended-Release tablets, 100 mg/1,000 mg, 50 mg/500 mg, and 50 mg/ 1,000 mg
Applicant/Sponsor Name:	Zydus Pharmaceuticals Inc. (Zydus)
TTT ID #:	2023-6512-1
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container labels received on January 23, 2024 for Zituvimet XR. The Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the revised container labels for Zituvimet XR (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

The Applicant implemented all of our recommendations and we have no additional recommendations at this time.

[a] Patel, V. Label and Labeling Review for Zituvimet XR (NDA 216778). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2023 Dec 28. TTT ID No.: 2023-6512.

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VRAJ K PATEL
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DAMON A BIRKEMEIER
01/25/2024 09:19:39 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)

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Date of This Review:	December 28, 2023
Requesting Office or Division:	Division of Diabetes, Lipid Disorders, and Obesity (DDLO)
Application Type and Number:	NDA 216778
Product Name, Dosage Form, and Strength:	Zituvimet XR (sitagliptin and metformin hydrochloride) Extended-Release tablets, 100 mg/1,000 mg, 50 mg/500 mg, and 50 mg/ 1,000 mg
Product Type:	Multi-Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Zydus Pharmaceuticals Inc. (Zydus)
FDA Received Date:	September 22, 2023
TTT ID #:	2023-6512
DMEPA 1 Safety Evaluator:	Vraj Patel, PharmD
DMEPA 1 Team Leader:	Damon Birkemeier, PharmD, FISMP, NREMT

REASON FOR REVIEW

As part of the approval process for Zituvimet XR (sitagliptin and metformin hydrochloride) Extended-Release tablets, the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) requested that we review the proposed Zituvimet XR prescribing information (PI), medication guide, and container labels for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

NDA 216778 is a 505(b)(2) NDA and the listed drug product is Janumet XR (sitagliptin and metformin hydrochloride), NDA 202270.

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

1 CONCLUSION AND RECOMMENDATIONS

The proposed medication guide is acceptable from a medication error perspective. However, the proposed PI and container labels 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 Table 2 for Zydus Pharmaceuticals Inc. (Zydus).

RECOMMENDATIONS FOR ZYDUS PHARMACEUTICALS INC. (ZYDUS)

Table 2. Identified Issues and Recommendations for Zydus Pharmaceuticals Inc. (Zydus) (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
Container Label(s)			
1.	We note you propose two distinct expiration date formats: (b) (4) 	Clearly defining the expiration date will minimize confusion and risk for deteriorated drug medication errors.	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 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.	For the 50 mg/500 mg and 50 mg/1,000 mg strengths, the recommended dose statement (i.e., (b) (4) (b) (4) Two tablets taken once daily with a meal preferably in the evening. (b) (4) (b) (4) (b) (4)) on	To ensure consistency with the terminology in the Prescribing Information.	Revise the recommended dose statement for the 50 mg/500 mg and 50 mg/1,000 mg strength container labels to read, "Recommended Dosage: Two tablets taken once daily with a meal preferably in the evening. See Prescribing Information."

Table 2. Identified Issues and Recommendations for Zydus Pharmaceuticals Inc. (Zydus) (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	**RATIONALE FOR CONCERN**	**RECOMMENDATION**
	the container labels is inconsistent with the terminology in the Prescribing Information.		
3.	The 100 mg/1,000 mg strength statement of dosage terminology (i.e., (b) (4) tablet (b) (4) taken once daily with a meal preferably in the evening. (b) (4) (b) (4) (b) (4)) on the container label is inconsistent with the terminology and information in the Prescribing Information.	To ensure consistency with the terminology in the prescribing information. Additionally, we note that Section 2 Dosage and Administration of the PI states, "The maximum recommended daily dose is 100 mg of sitagliptin and 2,000 mg of metformin hydrochloride (HCl) extended release." (b) (4)	Revise the statement recommended dose statement for the 100 mg/1,000 mg strength container label to read, "Recommended Dosage: One tablet taken once daily with a meal preferably in the evening. See Prescribing Information."
4.	As currently presented, the net quantity statement and the Rx Only statement on the principal display panel (PDP) compete for prominence with important information such as the medication strength.	The net quantity statement and the Rx Only statement should not complete in size and prominence with critical information on the PDP.	We recommend debolding the "Rx Only" statement and the net quantity to decrease prominence compared to the strength statement.

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table presents relevant product information for Zituvimet XR that Zydus Pharmaceuticals Inc. (Zydus) submitted on September 22, 2023, and the listed drug (LD).

Table 4. Relevant Product Information for Listed Drug and Zituvimet XR		
Product Name	Janumet XR[a]	Zituvimet XR
Initial Approval Date	February 02, 2012	N/A
Active Ingredient	sitagliptin and metformin hydrochloride extended-release	
Indication	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus	
Route of Administration	Oral	
Dosage Form	Extended-Release Tablet	
Strength	100 mg/1,000 mg; 50 mg/500 mg; 50 mg/1,000 mg	
Dose and Frequency	• Take orally once daily with a meal. Patients taking two tablets should take the tablets together. • The maximum recommended daily dose is 100 mg sitagliptin and 2,000 mg of metformin HCl extended-release. • The recommended starting dose in patients not currently treated with metformin is 100 mg sitagliptin and 1,000 mg metformin HCl once daily, with gradual dose escalation recommended to reduce the gastrointestinal effects due to metformin. • The starting dose in patients already treated with metformin should provide sitagliptin dosed as 100 mg and the dose of metformin already being taken once daily. For patients taking metformin HCl 850 mg twice daily or 1,000 mg twice daily, the recommended starting dose of ZITUVIMET XR is two 50 mg sitagliptin and 1,000 mg metformin HCl extended-release tablets once daily. • Maintain the same total daily dose of sitagliptin and metformin when changing between Janumet and Zituvimet XR.	

[a] Janumet XR [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. June 2022. [cited 2023 Dec 11]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/202270s026lbl.pdf.

Table 4. Relevant Product Information for Listed Drug and Zituvimet XR

Product Name	Janumet XR[a]	Zituvimet XR
How Supplied	See nested table below	See nested table below
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.]. Store in a dry place with cap tightly closed.	

Janumet XR[a] — How Supplied

Contents	Description	How Supplied
50 mg sitagliptin and 500 mg metformin HCl extended-release	light blue, bi-convex oval, film-coated tablets with "78" debossed on one side	unit-of-use bottles of 60
		unit-of-use bottles of 180
		bulk bottles of 1000
50 mg sitagliptin and 1000 mg metformin HCl extended-release	light green, bi-convex oval, film-coated tablets with "80" debossed on one side	unit-of-use bottles of 60
		unit-of-use bottles of 180
		bulk bottles of 1000
100 mg sitagliptin and 1000 mg metformin HCl extended-release	blue, bi-convex oval, film-coated tablets with "81" debossed on one side	unit-of-use bottles of 30
		unit-of-use bottles of 90
		bulk bottles of 1000

Zituvimet XR — How Supplied

Contents	Description	How Supplied
50 mg sitagliptin and 500 mg metformin HCl extended-release	Light orange to beige colored, oval shaped, film-coated tablets debossed with "1804" on one side and plain on the other side.	unit-of-use bottles of 60 (b) (4)
50 mg sitagliptin and 1,000 mg metformin HCl extended-release	Yellow to beige colored, oval shaped, film-coated tablets debossed with "1805" on one side and plain on the other side.	unit-of-use bottles of 60
100 mg sitagliptin and 1,000 mg metformin HCl extended-release	Reddish brown to brown colored, oval shaped, film-coated tablets debossed with "1806" on one side and plain on the other side.	unit-of-use bottles of 30

APPENDIX B. PREVIOUS DMEPA REVIEWS

On December 7, 2023, we searched for previous DMEPA reviews relevant to this current review using the terms, “NDA 216778”. Our search identified no 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 Zituvimet XR labels and labeling submitted by Zydus Pharmaceuticals Inc. (Zydus).

- Container label(s) received on September 22, 2023
- Carton labeling received on September 22, 2023
- Medication Guide received on September 22, 2023, available from \\CDSESUB1\EVSPROD\nda216778\0007\m1\us\med-guide.pdf
- Prescribing Information (Image not shown) received on September 22, 2023, available from \\CDSESUB1\EVSPROD\nda216778\0007\m1\us\pi.pdf

F.2 Label and Labeling Images

Container label(s)

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

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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: 12/4/2023

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 216778

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

Cliantha, Vadodara: ORA conducted an inspection for the clinical site in July 2022. The inspection was conducted under the following submission: ANDA (b) (4)

OSIS concluded that data from the reviewed studies were reliable.

OSIS notes that this site is permanently closed.

(b) (4): OSIS conducted a Remote Regulatory Assessment (RRA) for the analytical site in . The RRA was conducted under the following submissions: ANDAs (b) (4) and (b) (4)

OSIS concluded that data from the reviewed studies were reliable.

Sites

Facility Type	Facility Name	Facility Address
Clinical	Cliantha Research, Ltd.	1st Floor, Silver Arcade, Near Ashwamegh III, Samrajya, Mujmahuda Road, Akota, Vadodara, Gujarat, India
Analytical	(b) (4)	

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