CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218139Orig1s000

OTHER REVIEW(S)

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

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

Memorandum

Date: June 24, 2024

To: Sydney Tran, Regulatory Project Manager
Division of Urology, Obstetrics, and Gynecology (DUOG)

Marjorie Dannis, Clinical Reviewer, DUOG

From: Elvy Varghese, Regulatory Review Officer
Office of Prescription Drug Promotion (OPDP)

Meena Savani, Regulatory Review Officer, OPDP

CC: James Dvorsky, Team Leader, OPDP

Sapna Shah, Team Leader, OPDP

Subject: OPDP Labeling Comments for TEZRULY (terazosin) oral solution

NDA: 218139

Background:

In response to DUOG's consult request dated November 7, 2023, OPDP has reviewed the proposed Prescribing Information (PI), Patient Package Insert (PPI and carton and container labeling for the original NDA submission for TEZRULY (terazosin) oral solution [Tezruly].

PI/PPI:

OPDP's review of the proposed PI is based on the draft labeling emailed to OPDP on June 12, 2024, 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 on June 21, 2024.

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 18, 2024, and our comments are provided below.

Thank you for your consult. If you have any questions, please contact Elvy Varghese at Elvy.Varghese@fda.hhs.gov and Meena Savani at Meena.Savani@fda.hhs.gov.

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

---

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/

ELVY M VARGHESE
06/24/2024 03:18:45 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:	June 21, 2024
To:	Sydney Tran, PharmD Regulatory Project Manager **Division of Urology, Obstetrics, and Gynecology (DUOG)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)**
From:	Nyedra W. Booker, PharmD, MPH Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Elvy Varghese, PharmD. Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Patient Package Insert (PPI)
Drug Name (established name):	TEZRULY (terazosin)
Dosage Form and Route:	oral solution
Application Type/Number:	NDA 218139
Applicant:	Novitium Pharma LLC

1 INTRODUCTION

On September 29, 2023, Novitium Pharma LLC submitted for the Agency's review an original New Drug Application (NDA) for TEZRULY (terazosin) oral solution. The Applicant is proposing a 1mg/mL oral solution for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH) and hypertension alone or with other antihypertensive agents, to lower blood pressure.

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 Urology, Obstetrics and Gynecology (DUOG) on November 7, 2023 and November 7, 2023, for DMPP and OPDP to review the Applicant's proposed Patient Package Insert (PPI) for TEZRULY (terazosin) oral solution.

2 MATERIAL REVIEWED

- Draft TEZRULY (terazosin) oral solution PPI received on September 29, 2023, revised by the Review Division throughout the review cycle, and received by DMPP on June 12, 2024.
- TEZRULY (terazosin) oral solution PPI received on September 29, 2023, revised by the Review Division throughout the review cycle, and received by OPDP on June 12, 2024.
- Draft TEZRULY (terazosin) oral solution Prescribing Information (PI) received on September 29, 2023, revised by the Review Division throughout the review cycle, and received by DMPP on June 12, 2024.
- Draft TEZRULY (terazosin) oral solution Prescribing Information (PI) received on September 29, 2023, revised by the Review Division throughout the review cycle, and received by OPDP on June 12, 2024.

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 PPI document using the Arial font, size 10.

In our collaborative review of the PPI we:

- simplified wording and clarified concepts where possible
- ensured that the PPI is consistent with the Prescribing Information (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)
- ensured that the PPI is consistent with the approved comparator labeling where applicable.

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.

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

---

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/

NYEDRA W BOOKER
06/21/2024 09:20:20 AM

ELVY M VARGHESE
06/21/2024 09:27:34 AM

LASHAWN M GRIFFITHS
06/21/2024 09:31:39 AM

MEMORANDUM
REVIEW OF REVISED LABEL AND LABELING

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	April 22, 2024
Requesting Office or Division:	Division of Urology, Obstetrics, and Gynecology (DUOG)
Application Type and Number:	NDA 218139
Product Name, Dosage Form, and Strength:	Tezruly (terazosin) oral solution, 1 mg/mL
Applicant Name:	Novitium Pharma LLC
FDA Received Date:	April 16, 2024
TTT ID #:	2023-6583-1
DMEPA 2 Safety Evaluator:	Rina Patel, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD

1 PURPOSE OF MEMORANDUM

Novitium Pharma LLC submitted a revised container label received on April 16, 2024 for Tezruly. The Division of Urology, Obstetrics, and Gynecology (DUOG) requested that we review the revised container label for Tezruly (Appendix A) to determine if it is 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

Novitium Pharma LLC implemented all of our recommendations and we have no additional recommendations at this time.

[a] Patel, R. Label and Labeling Review for Tezruly (NDA 218139). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 April 01. TTT ID: 2023-6583.

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

---

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/

RINA N PATEL
04/22/2024 08:17:43 AM

STEPHANIE L DEGRAW
04/22/2024 02:23:47 PM

LABEL AND LABELING REVIEW
Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	April 1, 2024
Requesting Office or Division:	Division of Urology, Obstetrics, and Gynecology (DUOG)
Application Type and Number:	NDA 218139
Product Name, Dosage Form, and Strength:	Tezruly (terazosin) oral solution, 1 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Novitium Pharma LLC
FDA Received Date:	September 29, 2023 and December 4, 2023
TTT ID #:	2023-6586
DMEPA 2 Safety Evaluator:	Rina Patel, PharmD
DMEPA 2 Team Leader:	Stephanie DeGraw, PharmD

1 REASON FOR REVIEW

As part of the approval process for Tezruly (terazosin) oral solution, the Division of Urology, Obstetrics, and Gynecology (DUOG) requested that we review the proposed Tezruly Prescribing Information (PI), Patient Information, and container label for areas of vulnerability that may lead to medication errors.

1.1 BACKGROUND

NDA 218139 is a 505(b)(2) NDA and the listed drug product is Hytrin, NDA 020347.

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 (N/A)
ISMP Newsletters*	C (N/A)
FDA Adverse Event Reporting System (FAERS)*	D (N/A)
Proposed Recommendations for Section 2 of the PI	E
Information Requests	F
Labels and Labeling	G

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 prescribing information (PI), Patient Information, and container label 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 Novitium Pharma LLC.

4 RECOMMEDATIONS FOR DIVISION OF UROLOGY, OBSTETRICS, AND GYNECOLOGY (DUOG)

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)

	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Prescribing Information – General Issues			
1.	The established name of the product is presented as "terazosin" in the product title but as the salt form "terazosin hydrochloride" throughout the prescribing information (PI). Further, "terazosin hydrochloride" does not correlate with the proposed strength (i.e., the strength is based on the active moiety, not the salt form).	The USP Salt Policy became effective on May 1, 2013, and USP is now applying it to all new drug product monographs for products that contain an active ingredient that is a salt. It affects the development of new drug products, because a USP monograph title for a new drug product, in most instances, serves as the nonproprietary or "established" name of the related drug product. A drug product with a label or labeling that contains a name that is inconsistent with the applicable monograph title risks being misbranded. For more information, see FDA Guidance for Industry Naming of Drug Products Containing Salt Drug Substances available at https://www.fda.gov/media/87247/download	The established name should be revised to "terazosin" throughout the PI per the USP Salt Policy.
Highlights of Prescribing Information (HPI)			
1.	The dosage form information is presented inconsistently in the HPI (b) (4) vs. oral solution).	The dosage form should be presented consistently throughout the labeling to prevent confusion.	We recommend revising the product title to read "Tezruly (terazosin) oral solution" to align with the other areas of the PI and container label. We also recommend removing (b) (4)

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			(b) (4) We defer to OPQ regarding the final product title.
2.	The Dosage and Administration section of the HPI contains information that may not be relevant.	This section of the HPI should contain important dosing information in a way that is easy to find.	Consider removing the statement (b) (4) We defer to DUOG/clinical on the acceptability of this statement in the HPI Dosage and Administration section.
3.	The product strength is stated as (b) (4) in the Dosage Forms and Strengths section of the HPI whereas the strength is stated as "1 mg/mL" in the FPI and on the container label.	Consistent formatting of important information, such as the strength, can help minimize confusion.	We recommend revising the strength in the HPI to read "1 mg/mL".
Full Prescribing Information – Section 2 Dosage and Administration			
1.	The dosage information may be improved for readability and clarity.	Improved readability makes it easier to find important information.	Consider revising the dosage information. For example, - Remove the statement (b) (4) . - Remove the statement (b) (4) in section 2.2. - Change the word. (b) (4) to "restarted".

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			See Appendix E for our full proposed recommendations for Section 2 of the PI for the Division's consideration.
2.	The unit of measure for dose (mg) and time (hours) is not present after each numerical value.	Including units of measurement with each numerical unit will help mitigate potential dosing errors.	We recommend adding the unit 'kg' and 'hours' after each numerical value as appropriate. See Appendix E.
3.	As currently presented, the subsection headings in Section 2 could be improved for clarity.	Clear headings can help the prescriber find important information and prevent wrong dosage errors.	We recommend revising the headings to read as follows: 2.1 Recommended Dosage for Benign Prostatic Hyperplasia 2.2 Recommended Dosage for Hypertension
4.	The frequency of administration information can be improved for clarity in section 2.1 and 2.2.	Clarifying the frequency of administration may decrease the risk of wrong frequency of administration errors.	We recommend modifying (b) (4) to "1 mg once daily at bedtime."
5.	The route of administration is missing from the dosage statement.	Omitting important information such as the route of administration may lead to administration medication errors.	We recommend adding the route of administration under a new subsection "2.3 Administration Information". See Appendix E.
6.	As currently presented, the statement (b) (4) is located in the beginning of Section 2.	To find information easily, we recommend moving administration information into an appropriately labeled section.	We recommend moving this information under a new subsection "2.3 Administration Information". See Appendix E.
7.	Information on how to measure the appropriate dose is missing.	Selecting an unacceptable measuring device may increase the risk for wrong dose medication errors.	We propose specifying acceptable types of measuring devices under a new subsection "2.3 Administration Information". For example, "A calibrated measuring device, such as an oral

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			syringe or oral dosing cup, is recommended to measure and deliver the prescribed dose accurately. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device." See Appendix E.
8.	The statement "If TEZRULY is discontinued for more than a few days, therapy should be reinstituted using the initial dosing regimen" is present in three places in Section 2.	It is important to reduce redundancy. Further, the OND labeling review tool recommends "placing information under subsection(s) instead of inserting information between the section heading and first subsection heading."	Consider removing the statement from the beginning of section 2. See Appendix E.
Full Prescribing Information – Section 3 Dosage Forms and Strengths			
1.	As currently presented, the strength of the product is listed towards the end of the sentence.	The most important information should be listed in the beginning in order to increase prominence.	We recommend moving the strength information to the beginning of the sentence. For example, "TEZRULY 1 mg/mL oral solution…".
2.	The bottle size information is presented in this section.	The bottle size is not required in this section and may cause confusion.	We recommend removing (b) (4) from Section 3. This information is present in Section 16.
Full Prescribing Information – Section 16 How Supplied/Storage and Handling			
1.	As currently presented, the strength of the product is listed towards the end of the sentence. We also note that the established name is missing.	The most important information should be listed in the beginning in order to increase prominence.	We recommend moving the strength information to the beginning of the sentence and adding the established name. For example, "TEZRULY 1 mg/mL terazosin oral solution…".

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
2.	The Storage and Handling Statement is worded differently compared to the statement present on the container label.	The language should align with the statement used on the container label to prevent confusion and wrong storage errors.	We recommend revising the storage statement to read "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]." However, we ultimately defer to OPQ to determine the appropriate storage statement.
Full Prescribing Information – Section 17 Patient Counseling			
1.	As currently presented, no statement is present to instruct patients or their caregivers to use a calibrated oral dosing device to measure the appropriate dose.	Selecting an unacceptable measuring device may increase the risk for wrong dose medication errors.	We propose specifying acceptable types of measuring devices. For example, "Inform patients that a calibrated measuring device, such as an oral syringe or oral dosing cup, should be obtained from the pharmacy to measure and deliver the prescribed dose accurately. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device."
Patient Information			
1.	As currently presented, the route of administration is missing.	Omitting information such as the route of administration may lead to administration medication errors.	We recommend adding the route of administration to the "How should I take TEZRULY" section.
2.	As currently presented, no statement is present to instruct patients or their caregivers to use a calibrated oral dosing device to measure the appropriate dose.	Selecting an unacceptable measuring device may increase the risk for wrong dose medication errors.	We propose specifying acceptable types of measuring devices under the "How should I take TEZRULY" section. For example, "A calibrated measuring device, such as an oral syringe or oral dosing cup, should be obtained from the pharmacy

Table 2. Identified Issues and Recommendations for Division of Urology, Obstetrics, and Gynecology (DUOG)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
			to measure and deliver the prescribed dose accurately. A household measuring cup, teaspoon, or tablespoon is not an adequate measuring device."
3.	The "How should I take TEZRULY?" section contains specific dose information. Specifically, it states "The starting dose of TEZRULY is (b) (4) 1 mg".	Patients should follow the dosing regimen prescribed by the healthcare provider.	We recommend not including specific dosing in the patient information; however, we defer to DUOG and DMPP/PLT on the appropriateness of including the starting dose in the Patient Information. If appropriate to keep, we recommend removing (b) (4) since the dose in mL ("1 mL") is already provided. See Guidance for Industry: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors (May 2022).*
4.	As currently presented, the "How should I take TEZRULY" section contains the error-prone abbreviation (b) (4).	Error prone abbreviations may lead to misinterpretation and medication error.	

5 RECOMMENDATIONS FOR NOVITIUM PHARMA LLC

Table 3. Identified Issues and Recommendations for Novitium Pharma LLC (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
Container Label			
1.	The terminology within the Recommended Dosage statements (i.e., (b) (4) on the carton and container is inconsistent with the	To ensure consistency with the terminology in the Prescribing Information.	We recommend revising the recommended dosage statements to read, "Dosage: see Prescribing Information."

Table 3. Identified Issues and Recommendations for Novitium Pharma LLC (entire table to be conveyed to Applicant)			
	IDENTIFIED ISSUE	RATIONALE FOR CONCERN	RECOMMENDATION
	terminology in the Prescribing Information.		
2.	The units of temperature measurement (Centigrade and Fahrenheit) following the first numbers in the temperature ranges are missing.	To improve clarity and align with the temperature ranges presented in the prescribing information.	Add the Centigrade symbol (C) following the 20° and 15° and the Fahrenheit symbol (F) following the 68° and 59° within the storage statement. For example, "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]."
3.	The route of administration statement contains the word (b) (4).	We reserve the use of the word (b) (4) when there is a safety concern or data that supports the product must be given by a specific route.	We recommend revising the route of administration statement so that it reads "For Oral Use".

APPENDICES: METHODS & RESULTS FOR EACH MATERIAL REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table presents relevant product information for Tezruly that Novitium Pharma LLC submitted on October 29, 2023, and the listed drug (LD).

Table 4. Relevant Product Information for Listed Drug and Tezruly

Product Name	Hytrin[a] (NDA 020347)	Tezruly
Initial Approval Date	December 14, 1994 Withdrawn FR Effective 8/19/13 generics available	N/A
Active Ingredient	terazosin hydrochloride	terazosin
Indication	• Treatment of benign prostatic hyperplasia (BPH) • Treatment of hypertension	
Route of Administration	Oral	
Dosage Form	Capsule	Oral solution
Strength	1 mg, 2 mg, 5 mg, 10 mg	1 mg/mL
Dose and Frequency	*Benign Prostatic Hyperplasia* - Initial dose: 1 mg at bedtime - Usual dose: 1 mg to 10 mg once daily - Maximum dose: 20 mg once daily *Hypertension* - Initial dose: 1 mg at bedtime - Usual dose: 1 mg to 5 mg once daily - Maximum dose: 20 mg once daily - If response is substantially diminished at 24 hours, may consider a twice daily regimen.	
How Supplied	- bottle of 100 capsules - unit dose strip packs (100 capsules)	150 mL solution in a bottle
Storage	Store at controlled room temperature between 20-25°C (68-77°F). See USP. Protect from light and moisture.	Store at room temperature between 20°C and 25°C (68°F and 77°F), allow excursions between 15°C and 30°C (59°F and 86°F).
Container Closure		Bottle with child resistant closure

[a] Hytrin (terazosin hydrochloride) [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. 2006 Feb 06. [cited 2023 Nov 21]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/19057Orig1s021,%2020347Orig1s009%20lbl.pdf.

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

---

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/

RINA N PATEL
04/01/2024 01:16:54 PM

STEPHANIE L DEGRAW
04/01/2024 03:36:22 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: 1/26/2024

TO: Division of Urology, Obstetrics, and Gynecology (DUOG)
Office of Rare Diseases, Pediatrics, Urology and Reproductive Medicine (ORPURM)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 218139

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

Rationale

The Office of Regulatory Affairs (ORA) conducted an inspection for the clinical site in August 2023. The inspection was conducted under the following submission: ANDA NON-RESPONSIVE

The following objectionable condition was observed:

- The general requirements for informed consent were not met in that the site did not seek consent under circumstances that minimized the possibility of coercion or undue influence.

After review of the objectionable condition and the written response from the site, OSIS recommended that the review division consider the totality of information in the informed consent firm to determine the impact on data reliability. (Final OSIS Review - August 2023).

Site

Facility Type	Facility Name	Facility Address
Clinical		(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/

WENDY NG
01/26/2024 06:46:17 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: 12/11/2023

TO: Division of Urology, Obstetrics, and Gynecology (DUOG)
Office of Rare Diseases, Pediatrics, Urology and Reproductive Medicine (ORPURM)

FROM: Office of Study Integrity and Surveillance (OSIS)

SUBJECT: **Decline to conduct an on-site inspection**

RE: NDA 218139

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

Rationale

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

OSIS concluded that data from the reviewed studies were reliable.

Site

Facility Type	Facility Name	Facility Address
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
12/11/2023 10:50:47 AM