CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761216Orig1s000

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)

Date of This Memorandum:	October 6, 2021
Requesting Office or Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761216
Product Name and Strength:	Yusimry "CHS-1420"[a] (adalimumab-aqvh)[b] Injection, 40 mg/0.8 mL
Applicant/Sponsor Name:	Coherus Biosciences
OSE RCM #:	2021-37-1
DMEPA 1 Safety Evaluator:	Teresa McMillan, PharmD
DMEPA 1 Team Leader:	Idalia E. Rychlik, PharmD

1 PURPOSE OF MEMORANDUM

The Applicant submitted revised container labels and carton labeling received on September 20, 2021 for Yusimry "CHS-1420". Division of Rheumatology and Transplant Medicine (DRTM) requested that we review the revised container labels and carton labeling for Yusimry "CHS-1420" (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.[c]

2 CONCLUSION

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

[a] CHS-1420 has been developed as a proposed biosimilar to US-licensed Humira (adalimumab). The proposed proprietary name for this BLA, Yusimry, was found conditionally acceptable on March 24, 2021.
[b] The nonproprietary name, adalimumab-aqvh, was found conditionally acceptable on January 29, 2020 (under IND 119540).

[c] McMillan, T. Label and Labeling Review for Yusimry "CHS-1420" (BLA 761216). Silver Spring (MD): FDA, CDER, OSE, DMEPA 1 (US); 2021-AUG 11. RCM No.: 2021-37.

APPENDIX A. IMAGES OF LABEL AND LABELING RECEIVED ON SEPTEMBER 20, 2021

Container labels

Tray label

\\CDSESUB1\evsprod\bla761216\0020\m1\us\chs-1420-pfs-ff-tray-label.pdf

Syringe label

\\CDSESUB1\evsprod\bla761216\0020\m1\us\chs-1420-pfs-ff-syringe-label.pdf

Carton labeling

\\CDSESUB1\evsprod\bla761216\0020\m1\us\chs-1420-pfs-ff-carton-label.pdf

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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: September 23, 2021

TO: Nikolay Nikolov, M.D.
Director
Division of Rheumatology and Transplant Medicine
Office of New Drugs

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

Amanda Lewin, Ph.D.
Division of Generic Drug Study Integrity (DGDSI)
OSIS

THROUGH: Charles Bonapace, Pharm.D.
Director
DNDSI
OSIS

SUBJECT: Remote Record Review (RRR) of [redacted] (b) (4)

1. RRR Summary

OSIS conducted an RRR of the analytical portion of Study CHS-1420-03 (BLA 761216, CHS-1420) performed at [redacted] (b) (4) An on-site inspection was not possible due to the disruption of inspectional activities by the COVID-19 global pandemic.

We observed the following objectionable condition during the RRR:

[redacted] (b) (4)

1.1. Recommendation

Based on the outcome of the RRR and review of the firm's response, the objectionable condition had no impact on the integrity of the pharmacokinetic (PK) data reviewed from Study

CHS-1420-03. Therefore, we conclude that the PK concentration data from the reviewed study are reliable.

2. Reviewed Study

Application Number: BLA 761216
Study Number: CHS-1420-03
Study Title: "A randomized, double-blind, single-dose, parallel-group study to assess the pharmacokinetic similarity of CHS-1420 DP and Humira® (US) in healthy Male and Female subjects."
PK Sample Analysis Period: January 10 to February 6, 2017

3. Scope of RRR

OSIS scientists [redacted] (b) (4) reviewed the analytical portion of the above study during the RRR at [redacted] (b) (4)

The RRR included opening and close-out meetings with the firm using Zoom. Requests for documents were made and a file hosting service [redacted] (b) (4) was used to receive documents directly from the firm. The RRR team used screen sharing capabilities to review study data when clarifications were needed. The current RRR included an audio/video remote facility tour of study-relevant areas, examination of records for method validation, sample analysis, receipt/storage of PK study samples, and interviews with the firm's management and staff. In addition, selected study-relevant standard operating procedures (SOPs), an index of SOPs, the organizational charts, and the floor plans of the facility were reviewed.

4. RRR Observations

At the conclusion of the RRR, we observed one objectionable condition. We discussed the following observation with the firm's management during the RRR close-out meeting.

Our evaluation of the observation and the firm's response dated [redacted] (b) (4) (**Attachment-1**) are presented below.

4.1. Observation discussed at the close-out of RRR

[redacted] (b) (4)

(b) (4)

5. Conclusion

Based on the outcome of the RRR and review of the firm's response, the objectionable conditions had no impact on the integrity of the PK data reviewed from Study CHS-1420-03. Therefore, we conclude that the PK concentration data from the reviewed study are reliable.

Gajendiran Mahadevan, Ph.D.
Pharmacologist
DNDSI/OSIS

Amanda Lewin, Ph.D.
Lead Pharmacologist

DGDSI/OSIS

cc:
OTS/OSIS/Kassim/Folian/Pham/Mitchell/Fenty-Stewart/Haidar/Mirza
OTS/OSIS/DNDSI/Bonapace/Ayala/Biswas/Mahadevan
OTS/OSIS/DGDSI/Dasgupta/Benson/Skelly/Au/Lewin

Draft: GM 9/17/2021, 9/21/2021, 9/23/2021; AL 9/21/2021
Edit: RCA 9/21/2021; CB 9/21/2021

ECMS: http://ecmsweb.fda.gov/webtop/drl/objectId/0b0026f884a31cbd
OSIS File #: BE 9052

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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:	September 15, 2021
To:	Elaine Sit, PharmD Regulatory Health Project Manager **Division of Rheumatology and Transplant Medicine (DRTM)**
Through:	LaShawn Griffiths, MSHS-PH, BSN, RN Associate Director for Patient Labeling **Division of Medical Policy Programs (DMPP)** Sharon Williams, MSN, BSN, RN Senior Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)**
From:	Lonice Carter, MS, RN, CNL Patient Labeling Reviewer **Division of Medical Policy Programs (DMPP)** Adewale Adeleye, Pharm.D., MBA Regulatory Review Officer **Office of Prescription Drug Promotion (OPDP)**
Subject:	Review of Patient Labeling: Medication Guide (MG), Instructions for Use (IFU), and Quick Reference Guide (QRG)
Drug Name (nonproprietary name):	[CHS-1420] YUSIMRY (adalimumab-aqvh)[1]
Dosage Form and Route:	injection, for subcutaneous use
Application	BLA 761216

[1] CHS-1420 has been developed as a proposed biosimilar to US-licensed Humira (adalimumab). The proposed proprietary name for this BLA, Yusimry, was found conditionally acceptable on March 24, 2021. The nonproprietary name, adalimumab-aqvh, was found conditionally acceptable on January 29, 2020 (under IND 119540).

Type/Number:

Applicant: Coherus BioSciences, Inc.

1 INTRODUCTION

On December 18, 2020, Coherus BioSciences, Inc. submitted for the Agency's review an original Biologics License Application (BLA) 761216 for YUSIMRY (adalimumab-aqvh) injection, for subcutaneous use, a proposed biosimilar to US-licensed HUMIRA (adalimumab) BLA 125057. This BLA proposes the following indications:

- Rheumatoid Arthritis (RA): Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA
- Juvenile Idiopathic Arthritis (JIA): Reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older.
- Psoriatic Arthritis (PsA): Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA
- Ankylosing Spondylitis (AS): Reducing signs and symptoms in adult patients with active AS
- Crohn's Disease (CD): Treatment of moderately to severely active Crohn's disease in adult and pediatric patients 6 years of age and older
- Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adult patients
- Plaque Psoriasis (PsO): Treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate

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 Rheumatology and Transplant Medicine (DRTM) on January 26, 2021 and January 12, 2021 respectively, for DMPP and OPDP to review the Applicant's proposed Medication Guide (MG), Instructions for Use (IFU), and Quick Reference Guide (QRG) for YUSIMRY (adalimumab-aqvh) injection, for subcutaneous use.

2 MATERIAL REVIEWED

- Revised draft YUSIMRY (adalimumab-aqvh) MG, IFU, and QRG received on May 6, 2021, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on July 28, 2021.

- Revised draft YUSIMRY (adalimumab-aqvh) Prescribing Information (PI) received on May 6, 2021, revised by the Review Division throughout the review cycle, and received by DMPP and OPDP on July 28, 2021.
- Approved US-licensed HUMIRA (adalimumab) comparator labeling dated February 24, 2021.

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 MG, IFU, and QRG we:

- simplified wording and clarified concepts where possible
- ensured that the MG, IFU, and QRG are consistent with the Prescribing Information (PI)
- removed unnecessary or redundant information
- ensured that the MG, IFU, and QRG are free of promotional language or suggested revisions to ensure that it is free of promotional language
- ensured that the MG meets the Regulations as specified in 21 CFR 208.20
- ensured that the MG, IFU, and QRG meet the criteria as specified in FDA's Guidance for Useful Written Consumer Medication Information (published July 2006)
- ensured that the MG and IFU are consistent with the approved comparator labeling where applicable.

4 CONCLUSIONS

The MG, IFU, and QRG are acceptable with our recommended changes.

5 RECOMMENDATIONS

- Please send these comments to the Applicant and copy DMPP and OPDP on the correspondence.
- Our collaborative review of the MG, IFU, and QRG 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, IFU, and QRG.

Please let us know if you have any questions.

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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)

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

Date of This Review:	August 11, 2021
Requesting Office or Division:	Division of Rheumatology and Transplant Medicine (DRTM)
Application Type and Number:	BLA 761216
Product Name, Dosage Form, and Strength:	Yusimry "CHS-1420" [a] (adalimumab-aqvh) [b] Injection, 40 mg/0.8 mL
Product Type:	Combination Product (Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Coherus Biosciences
FDA Received Date:	December 19, 2020 and May 6, 2021
OSE RCM #:	2021-37
DMEPA 1 Safety Evaluator:	Teresa McMillan, PharmD
DMEPA 1 Team Leader:	Idalia Rychlik, PharmD

[a] CHS-1420 has been developed as a proposed biosimilar to US-licensed Humira (adalimumab). The proposed proprietary name for this BLA, Yusimry, was found conditionally acceptable on March 24, 2021.

[b] The nonproprietary name, adalimumab-aqvh, was found conditionally acceptable on January 29, 2020 (under IND 119540).

1 REASON FOR REVIEW

As part of the approval process for Yusimry (adalimumab-aqvh) Injection, the Division of Rheumatology and Transplant Medicine (DRTM) requested that we review the proposed Yusimry prescribing information (PI), Instructions for Use (IFU), container labels, and carton labeling for areas of vulnerability that may lead to medication errors.

1.1 REGULATION HISTORY AND BACKGROUND

Yusimry (adalimumab-aqvh) Injection (BLA 761216) is submitted for the purposes of licensure under Section 351(k) of the Public Health Service Act as a proposed biosimilar to US-licensed Humira (adalimumab).

DMEPA previously reviewed the Sponsor's submitted Use Related Risk Assessment (URRA) and comparative analyses (CA), for the proposed combination product, in OSE Review #2019-1420[c] under IND 119540 and determined the following:

Considering the totality of the information provided between CHS-1420 prefilled syringe and the reference product, US-licensed Humira, we agree with the Sponsor's determination that they do not need to submit the results of a human factors (HF) validation study as part of the marketing application. The URRA shows that the tasks are similar between the products, the known use-related risks are the same, and the proposed product does not appear to introduce any new or differing risks. The comparative analyses identified differences that may impact critical tasks; however, based on additional considerations described above, we determined in this particular instance, these differences do not warrant the submission of HF testing information in the marketing application.

From a medication error perspective, there are no differences between the Instructions for Use that was previously reviewed under IND 119540 and that which is now being proposed under BLA 761216.

2 MATERIALS REVIEWED

We considered the materials listed in Table 1 for this review. The Appendices provide the methods and results for each material reviewed.

Table 1. Materials Considered for this Review	
Material Reviewed	Appendix Section (for Methods and Results)
Product Information/Prescribing Information	A

[c] Barlow, M.. Label and Labeling Review for CHS-1420 (IND 119540). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 04 09. RCM No.: 2019-2255.

Table 1. Materials Considered for this Review	
Material Reviewed	Appendix Section (for Methods and Results)
Previous DMEPA Reviews	B
Human Factors Study	C-N/A
ISMP Newsletters*	D – N/A
FDA Adverse Event Reporting System (FAERS)*	E – N/A
Other	F-N/A
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 FINDINGS AND RECOMMENDATIONS

Table 2: Identified Issues and Recommendations for Coherus Biosciences (entire table to be conveyed to Applicant)

Container Labels and Carton Labeling			
1.	The terminology used to describe the recommended dosage are not consistently presented.	Lack of consistency of dosage terminology may contribute to dosing errors.	For consistency with the Prescribing Information (PI) consider revising (b) (4) to the following: Recommended dosage: See Prescribing Information
2.	The lot and expiration numbers are undefined.	Undefined lot and expiration numbers may lead to identification issues and deteriorated drug product issues.	As currently presented, the format for the expiration date is not defined. To minimize confusion and reduce the risk for deteriorated drug medication errors, identify the 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 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 forward slash or a hyphen be used to separate the portions of the expiration date. Define the lot number as well.
Container Label (prefilled syringe)			
1.	The package type term "Single-dose" has been omitted from the principal display panel.	Omission of this information may lead to administration errors.	Revise to include the package-type term "Single-Dose" beneath the route of administration.

4 CONCLUSION

Our evaluation of the proposed labels and labeling identified areas of vulnerability that may lead to medication errors. Above, we have provided recommendations in Table 2 for Coherus Biosciences. We ask that the Division convey Table 2 in its entirety to Coherus Biosciences so that recommendations are implemented prior to approval of this BLA.

APPENDICES: METHODS & RESULTS FOR EACH MATERIALS REVIEWED

APPENDIX A. PRODUCT INFORMATION/PRESCRIBING INFORMATION

Table 2 presents relevant product information for Yusimry received on December 19, 2020 and May 6, 2021 from Coherus Biosciences.

Table 2. Relevant Product Information for Yusimry	
Initial Approval Date	n/a
Nonproprietary Name	adalimumab-aqvh
Indication	Rheumatoid Arthritis (RA): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. Ankylosing Spondylitis (AS): reducing signs and symptoms in adult patients with active AS. Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older. Ulcerative Colitis (UC) : treatment of moderately to severely active ulcerative colitis in adult patients . Limitations of Use: Effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers. Plaque Psoriasis (Ps): treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.
Route of Administration	Subcutaneous
Dosage Form	Injection
Strength	40 mg/0.8 mL
Dose and Frequency	Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis: *Adults:* 40 mg every other week.

	Some patients with RA not receiving methotrexate may benefit from increasing the dosage to 40 mg every week or 80 mg every other week. **Juvenile Idiopathic Arthritis:** **Pediatric Weight 2 Years of Age and Older** / **Recommended Dosage** (b) (4) 30 kg (66 lbs) and greater — 40 mg every other week **Crohn's Disease:** *Adults*: 160 mg on Day 1 (given in one day or split over two consecutive days); 80 mg on Day 15; and 40 mg every other week starting on Day 29. *Pediatric Patients 6 Years of Age and Older:* **Pediatric Weight** / **Recommended Dosage** (**Days 1 and 15** / **Starting on Day 29**) (b) (4) 40 kg (88 lbs) and greater — Day 1: 160 mg (single dose or split over two consecutive days) Day 15: 80 mg — 40 mg every other week **Ulcerative Colitis:** *Adults:* 160 mg on Day 1 (given in one day or split over two consecutive days), 80 mg on Day 15 and 40 mg every other week starting on Day 29. Discontinue in patients without evidence of clinical remission by eight weeks (Day 57). **Plaque Psoriasis:** *80 mg initial dose, followed by 40 mg every other week starting one week after initial dose.*
How Supplied	Supplied as a preservative-free, sterile, clear to slightly opalescent, colorless to slightly yellow solution for subcutaneous administration. The following packaging configurations are available. • **Prefilled Syringe Carton - 40 mg/0.8 mL** YUSIMRY is supplied in a carton containing two dose trays. Each dose tray consists of a single-dose, 1 mL prefilled glass syringe with a fixed ½ inch needle, providing 40

	mg/0.8 mL of YUSIMRY. The needle cover is not manufactured from natural rubber latex. The NDC number is XXXX-XXXX-XX.
Storage	Do not use beyond the expiration date on the container. YUSIMRY must be refrigerated at 36°F to 46°F (2°C to 8°C). DO NOT FREEZE. Do not use if frozen, even if it has been thawed. Store in original carton until time of administration to protect from light. If needed, for example when traveling, YUSIMRY may be stored at room temperature up to a maximum of 77°F (25°C) for a period of up to 14 days, with protection from light. YUSIMRY should be discarded if not used within the 14-day period. Record the date when YUSIMRY is first removed from the refrigerator in the spaces provided on the carton and dose pack. Do not store YUSIMRY in extreme heat or cold.

APPENDIX B. PREVIOUS DMEPA REVIEWS

On July 1, 2021, we searched for previous DMEPA reviews relevant to this current review using the terms, Yusimry and CHS-1420. Our search identified one previous reviews[d], and we considered our previous recommendations to see if they are applicable for this current review.

[d] Barlow, M.. Label and Labeling Review for CHS-1420 (IND 119540). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 04 09. RCM No.: 2019-2255.

APPENDIX C. HUMAN FACTORS STUDY-n/a

APPENDIX D. ISMP NEWSLETTERS-n/a

APPENDIX E. FDA ADVERSE EVENT REPORTING SYSTEM (FAERS)-n/a

APPENDIX F. n/a

APPENDIX G. LABELS AND LABELING

G.1 List of Labels and Labeling Reviewed

Using the principles of human factors and Failure Mode and Effects Analysis,[e] along with postmarket medication error data, we reviewed the following Yusimry labels and labeling submitted by Coherus Biosciences.

- Container label received on May 6, 2021
- Carton labeling received on May 6, 2021
- Instructions for Use received on May 6, 2021, available from \\CDSESUB1\evsprod\bla761216\0008\m1\us\drft-chs-1420-pfs-ff-ifu.pdf

- Prescribing Information (Image not shown) received on May 6, 2021, available from \\CDSESUB1\evsprod\bla761216\0008\m1\us\drft-pi.docx

G.2 Label and Labeling Images

Container label- Tray and Syringe

\\CDSESUB1\evsprod\bla761216\0008\m1\us\chs-1420-pfs-ff-tray-label.pdf

[e] 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: 5/21/2021

TO: Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation

FROM: Division of New Drug Study Integrity (DNDSI)
Office of Study Integrity and Surveillance (OSIS)

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

RE: BLA 761216

The Division of New Drug Bioequivalence Evaluation (DNDBE) within the Office of Study Integrity and Surveillance (OSIS) determined that inspections are not warranted at this time for the sites listed below. The rationale for this decision is noted below.

Rationale

Medpace, Inc: The Office of Regulatory Affairs (ORA) inspected the site in January 2017.. The inspection was conducted under the following submission: BLA 761039 and the final classification was No Action Indicated (NAI). OSIS notes that the previously inspected studies were conducted within 1.5 years of the current study under BLA761216 and involved the same clinical investigator (Dr. Leela Vishabhendra).

West Coast Clinical Trials: ORA inspected the site in (b) (4), which falls within the surveillance interval. The inspection was conducted under the following submission: (b) (4). The final classification for the inspection was NAI.

Therefore, based on the rationale described above, inspections are not warranted at this time.

Inspection Sites

Facility Type	Facility Name	Facility Address
Clinical	Medpace, Inc.	Clinical Pharmacology Unit, 5355 Medpace Way, Cincinnati, OH
Clinical	West Coast Clinical Trials (WCCT) Global, Inc.	5630 Cerritos Avenue, Cypress, CA

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