Food and Drug Administration Establishment Inspection Report

Date Assigned: 06/15/2021 **Inspection Start Date:** 06/21/2021 **Inspection End Date:** 07/02/2021

Firm Name & Address: Revance Therapeutics Inc , 7555 Gateway Blvd Newark, CA 94560-1152 US

Firm Mailing Address: 7555 Gateway Blvd, Newark, CA 94560-1152 United States

FEI: 3007772056 **JD/TA:** 11 **County:** ALAMEDA **Est Size:** 1,000,000 - 4,999,999

Phone: (510)742-3517 **District:** CDER **Profiled:** Yes

Conveyance Type: **% Interstate:** **Inspectional Responsibility:**

Endorsement

This was a comprehensive Pre-License Inspection (PLI) of Revance Therapeutics, Inc., Newark, CA covering (b) (4) (b) (4) for the manufacture of both the drug substance and drug product. The inspection was conducted June 21, 2021 to July 2, 2021. The inspection was conducted by Carla J. Lundi, Investigator, CDER/OPQ/OQS and Joao Pedras-Vasconcelos, QBP Primary Assessor, CBER/OPQ/OBP. The inspection was conducted in accordance with CP 7346.832 Pre-Approval Inspections (PAC 46832M) and covered all three objectives of the PAI program: commercial readiness, conformance to the application, and data integrity audit.

This was the initial inspection of Revance Therapeutics, Inc. and the (b) (4) pplication submitted by the applicant. The inspection found (b) (4) has (b) (4) batches completed for the finished drug product however, WCB (b) (4) used for the manufacture of the DS and DP (b) (4) lots was identified as the root cause of rejected drug substance lots (b) (4) manufactured in (b) (4) (b) (4) respectively. The firm initiated CAPA 21-017 in May of 2020 to manufacture and qualify a new WCB which is not yet been completed as of the date of this inspection. The firm concluded the process filed for the manufacture of drug substanc osed redesign of the monitoring for Culture Growth Performance as a time course to align with the (b) (4) process at the (b) (4) processing steps as suggested in CAPA 21-017.

A 5-item FDA-483, Inspectional Observations, was issued to Abhay Joshi Ph.D., Chief Operating Officer July 2, 2021. Dr. Joshis full title was later reported as COO, President of R&D and Product Operations. Observations 1 & 2 are related to the firms lack of readiness for commercial production for the drug substance failures observed for lots (b) (4) Observation 3 is for the firms Quality Unit lack of oversight of a leased testing facility where the critical release and stability (b) (4) ests is conducted was not identified in the firms (b) (4) Observation 4 is identified a lack of appropriate yield calculations being performed at appropriate (b) (4) of the manufacturing process for the drug product; and Observation 5 identified the firms lack of control over laboratory analytical worksheets and accountability of media fill vials.

Several items were discussed during the inspection with the firms management after which they took immediate corrective actions. These are discussed in the Voluntary Corrections section of this report.

The closeout occurred on July 2, 2021. The firm objected to Observation 2 as they stated that in their view the current (b) (4) drug substance is the exact same process as proposed for (b) (4) and that the changes being implemented resulted from taking appropriate actions to address manufacturing deficiencies identified since 2020. Dr. Pedras-Vasconcelos explained that the firm has no approval of their process, and that the details of the current process differ from what was submitted to the (b) (4) file, so it is an incorrect assumption that changes made properly address the issue at this time of the PLI. The firm stated they intend to respond to the cited observation within 15-business days.

The initial field recommendation is withhold for lack of readiness for commercial manufacturing.

Endorsement Location:

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
	ET	Thuy T Nguyen	09/13/2021 06:05 PM ET

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Related Firm FEI: **Name & Address of Related Firm:**

Registration Type		Registration Dates		
DEV	Device	01/01/2021	02/01/2020	
DRG	Drug	03/01/2021	03/01/2020	01/01/2019

Establishment Type		Industry Code	
A	Importer/Broker	55	Pharm Necess & Ctnr For Drug/Bio
A	Importer/Broker	57	Bio & Licensed In-Vivo & In-Vitro Diag
A	Importer/Broker	65	Human and Animal Drugs
A	Importer/Broker	75	Chemistry
A	Importer/Broker	79	General & Plastic Surgery
A	Importer/Broker	80	General Hospital/Personal Use
A	Importer/Broker	88	Pathology
A	Importer/Broker	91	Toxicology
A	Importer/Broker	95	Light Emitting Non-Device Products
M	Manufacturer	62	Human and Animal Drugs
M	Manufacturer	65	Human and Animal Drugs

District Use Code:

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Firm Name & Address: Revance Therapeutics Inc , 7555 Gateway Blvd Newark, CA 94560-1152 US

Inspection Basis: Surveillance

Inspected Processes & District Decisions

PAC	Establishment Type	Products/ Process	MQSA	Reschedule Insp Date	Re-Inspection Priority	Inspection Conclusions
46832M	Manufacturer	(b) (4)				Correction Indicated (CI)

Final Decision?	District Decision Date	District Decision Type	District Decision Made By	Org Name
	09/13/2021	Official Action Indicated (OAI)	Lundi, Carla J	CDER-DIA

Remarks: initial inspection, (b) (4) pplication

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	09/13/2021	Official Action Indicated (OAI)	Lundi, Carla J	CDER-DIA

Remarks: initial inspection, (b) (4) Application

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Products Covered

Product Code	Est Type	Description	Additional Product Description
(b) (4)	Manufacturer	(b) (4) Human - Non/Rx Single Ingredient Small Volume Parenteral <(b) (4) ml	(b) (4)
(b) (4)	Manufacturer	(b) (4) Human - Rx/Single Ingredient Active Pharm Ingred/Chems for Further Manuf	

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Lundi, Carla J	BUR	ORAHQ	46832M	Manufacturer	(b) (4)	180
Pedras Vasconcel, Joao A	BUR	ORAHQ	46832M	Manufacturer		15
Lundi, Carla J	BUR	CDER-DIA	46832M	Manufacturer		100
Pedras Vasconcel, Joao A	BUR	ORAHQ	46832M	Manufacturer		180

Total Hours: 475

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Inspection Result

EIR Location **Trips Num**

Inspection Summary

This was a comprehensive Pre-License Inspection (PLI) of Revance Therapeutics, Inc., Newark, CA covering (b) (4) for the manufacture of both the drug substance and drug product. The inspection was conducted June 21, 2021 to July 2, 2021. The inspection was conducted by Carla J. Lundi, Investigator, CDER/OPQ/OQS and Joao Pedras-Vasconcelos, QBP Primary Assessor, CBER/OPQ/OBP. The inspection was conducted in accordance with CP 7346.832 Pre-Approval Inspections (PAC 46832M) and covered all three objectives of the PAI program: commercial readiness, conformance to the application, and data integrity audit.

This was the initial inspection of Revance Therapeutics, Inc. and the (b) (4) application submitted by the applicant. The inspection found (b) (4) has (b) (4) batches completed for the finished drug product however, WCB (b) (4) used for the manufacture of the DS and DP (b) (4) ots, was identified as the root cause of rejected drug substance lots (b) (4) manufactured in August of 2020 and September 2020 respectively. The firm initiated CAPA 21-017 in May of 2020 to manufacture and qualify a new WCB which is not yet been completed as of the date of this inspection. The firm concluded the process filed for the manufacture of drug substance lots was not adequate and a proposed redesign of the monitoring for Culture Growth Performance as a time course to align with the (b) (4) process at the (b) (4) processing steps as suggested in CAPA 21-017.

A 5-item FDA-483, Inspectional Observations, was issued to Abhay Joshi Ph.D., Chief Operating Officer July 2, 2021. Dr. Joshis full title was later reported as COO, President of R&D and Product Operations. Observations 1 & 2 are related to the firms lack of readiness for commercial production for the drug substance failures observed for lots (b) (4) Observation 3 is for the firms Quality Unit lack of oversight of a leased testing facility where the critical release and stability (b) (4) ests is conducted was not identified in the firms (b) (4) Observation 4 is identified a lack of appropriate yield calculations being performed at appropriate (b) (4) of the manufacturing process for the drug product; and Observation 5 identified the firms lack of control over laboratory analytical worksheets and accountability of media fill vials.

Several items were discussed during the inspection with the firms management after which they took immediate corrective actions. These are discussed in the Voluntary Corrections section of this report.

The closeout occurred on July 2, 2021. The firm objected to Observation 2 as they stated that in their view the current (b) (4) drug substance is the exact same process as proposed for (b) (4) and that the changes being implemented ppropriate actions to address manufacturing deficiencies identified since 2020. Dr. Pedras-Vasconcelos explained that the firm has no approval of their process, and that the details of the current process differ from what was submitted to the (b) (4) file, so it is an incorrect assumption that changes made properly address the issue at this time of the PLI. It is recommended that an approval for (b) (4) be withheld for lack of commercial readiness. The firm stated they intend to respond to the cited observation within 15-business days.

IB Suggested Actions

Action **Remarks**

Referrals

Org Name **Mail Code** **Remarks**

Refusals

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Inspection Refusals: No refusal

Samples Collected

Sample Number

Recall Numbers

Recall Number

Related Complaints

Consumer Complaint Number

FDA 483 Responses

483 Issued?: Y **483 Location:**

Response Type	Response Mode	Response Date	Response Summary