DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	6/8/2026-6/17/2026* FEI NUMBER 3010477

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher S. Preti, CEO - CDMO

FIRM NAME	STREET ADDRESS
Jubilant HollisterStier LLC	3525 N Regal St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Spokane, WA 99207-5788	Drug Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

MATERIALS SYSTEM

OBSERVATION 1

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically, your firm does not always perform complete identification testing of raw materials (b) (4) and (b) (4) that is used as an ingredient in the manufacture of your (b) (4) injection and (b) (4) solution (diluent) products.

For (b) (4) and (b) (4) raw materials supplied to you by your client used in the manufacture of (b) (4) injection, an (b) (4) agent used in (b) (4) your firm relies solely on the client and raw material supplier's certificates of analysis (CoA) for the analysis of (b) (4) (b) (4)) and (b) (4) concentrations. Your firm only performs USP spectroscopic identification testing on (b) (4) and (b) (4) raw material supplied to you by your client.

The (b) (4) received by your firm ~~from your client,~~ is received in (b) (4) containers. Your

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firm samples and performs complete identification testing on (b) (4) for each (b) (4) lot received. At the conclusion of manufacturing finished product (b) (4) , your firm tests spent (b) (4) containers used in the manufacture of (b) (4) to confirm the identification of the material used. An analysis for (b) (4)) and (b) (4) concentrations is not performed using material from the spent (b) (4) containers used to manufacture (b) (4) . Also, these spent containers are not tested prior to manufacturing for identity or (b) (4) and (b) (4) concentrations.

OBSERVATION 2

Written procedures are not followed for the storage of components.

Specifically,

Your firm's written procedure (SOP 000497-R2, *Disposing of Obsolete/Outdated Warehouse Inventory*, Revision: 2, Effective Date: 30 Oct 2023) requires that materials reaching their retest or expiry date be physically segregated.

On 06/08/2026 and 06/12/2026, expired components were observed co-mingled with released raw materials, with no physical separation or quarantine designation including, but not limited to:

- (b) (4) API/USP, Batch: (b) (4) , Expiration Date: (b) (4)
- (b) (4) USP-NF, Batch: (b) (4) , Expiration Date: (b) (4)
- (b) (4) , Batch: (b) (4) , Expiration Date: (b) (4)
- (b) (4) , Batch: (b) (4) Expiration Date: (b) (4)

One (1) batch of (b) (4) API/USP, (Batch: (b) (4) , EXP: (b) (4)) was used in the

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manufacturing of (b) (4) (lot # (b) (4)) on (b) (4) and distributed on 03/31/2025.

(b) (4) batches of (b) (4) (batch: (b) (4) , EXP: (b) (4)) were used in the manufacturing of (b) (4) (i.e., lot (b) (4)) from 11/30/2025-12/30/2025.

(b) (4) batches of (b) (4) (Batch: (b) (4) , Expiration Date: (b) (4) were used in the manufacturing of (b) (4) (i.e., lot # (b) (4)) between 04/19/2022-04/11/2026.

PRODUCTION SYSTEM

OBSERVATION 3

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

Specifically, your quality unit failed to adequately investigate fourteen (14) recurring endotoxin out-of-specification (OOS) and out-of-trend (OOT) results at (b) (4) system (b) (4) (b) (4) and (b) (4) spanning July 2024 through January 2026.

These include, but are not limited to the following events:
2024: PR243379, PR248495, and PR252381
2025: PR268501, PR288414, and PR296936

The Quality Unit was unable to identify the source of these recurring failures and implemented CAPAs

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proved ineffective in preventing recurrence of failures. The source of endotoxin contamination has not been identified. The Quality Unit attributed the failures to biofilm growth and (b) (4) degradation. However, no root cause for the contamination source or the reason for (b) (4) integrity failure has been determined. Furthermore, investigations were not expanded to include adequate monitoring of the (b) (4) system downstream.

The (b) (4) system supplies the (b) (4) system, which is used in the manufacture of (b) (4) drug products on Lines (b) (4) and (b) (4) The approximate number of commercial drug products by manufacturing line and regulatory center is as follows:

Manufacturing Line	Regulatory Center	Approximate Number of Drug Products
(b) (4)	CDER	(b) (4)
	CBER	
	CDER	
	CBER	

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

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Specifically, the quality unit failed to requalify the existing (b) (4) system following the addition of an (b) (4) storage tank and (b) (4) in 2011. The (b) (4) system supplies the (b) (4) system, which is used in the manufacture of (b) (4) drug products.

A)No Installation Qualification (IQ), Operational Qualification (OQ), or Performance Qualification (PQ) was conducted for the (b) (4) storage tank (b) (4)), (b) (4) , (b) (4) (b) (4) ((b) (4)), or (b) (4) sterilizer (b) (4) .

B) In Critical Change Request (CCR) 11-177, the firm marked Validation/Revalidation as "Not Required" (NR) without providing justification.

C) (b) (4) sampling was redirected to new (b) (4) b) (4) and (b) (4) without re-establishing the validated state of the system at these locations.

D) No impact assessment was performed to evaluate the effect of the updated (b) (4) system on the (b) (4) system.

E) The quality unit failed to assess the suitability of materials of construction used in the updated (b) (4) system. Specifically, the (b) (4) storage tank (b) (4)) is constructed of (b) (4) and the (b) (4) is constructed of (b) (4) . No assessment was performed to determine whether these materials are suitable for use in a system that subsequently supplies (b) (4) to the (b) (4) system.

F) The firm has not established written specifications for (b) (4) and did not evaluate

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the impact of transitioning between (b) (4) types on the (b) (4) system or the (b) (4) system.

G) A dead leg was observed in the (b) (4) system.

LABORATORY SYSTEM

OBSERVATION 5

The sensitivity of test methods have not been established.

Specifically, the sensitivity of test methods has not been established.

Bacterial endotoxin testing (BET) samples are inadequately mixed, which may produce results that are not representative. On 06/12/2026 a BET of a (b) (4) sample was observed. The (b) (4) sample was collected on 06/11/2026 from (b) (4)(b) (4) on the (b) (4) which supports (b) (4) line (b) (4) During the testing process it was noted that the (b) (4)(b) (4) tubes used to collect the samples were majorly filled with sample volume. Prior to removing sample aliquots for testing, the samples were (b) (4) for approximately (b) (4) . It was observed that high sample volume did not allow for adequate sample mixing.

Products manufactured on line (b) (4) include CDER and CBER regulated drug products.

OBSERVATION 6

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Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans designed to assure that components conform to appropriate standards of identity, strength, quality and purity.

Specifically, the firm does not test or monitor (b) (4) quality at intermediate (b) (4) steps, after the (b) (4), or prior to the (b) (4) storage tank. The quality unit has not established monitoring for incoming (b) (4) quality across key chemical attributes, including, but not limited to, (b) (4) (b) (4), (b) (4) turbidity, (b) (4) levels, (b) (4), and (b) (4). No sampling (b) (4) or monitoring points are established downstream of (b) (4) equipment, including the (b) (4), and (b) (4) unit.

This (b) (4) supplies the (b) (4)) system, which is used in the manufacture of parenteral drug products.

The firm's current monitoring of the (b) (4) system and incoming (b) (4) is limited to (b) (4) sampling locations, as defined in SOP 015665, titled "EM Sampling: Utility Sampling," Revision 10:

(b) (4)

OBSERVATION 7
Established test procedures are not followed.

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Specifically, your firm conducts reprocessing of laboratory analytical samples without following firm procedures, for example:

A. On 06/15/2026 I reviewed SOP-001186 (b) (4) Bacterial Endotoxin Test: (b) (4) Method", revision 22, which describes the in-vitro assay for the detection and quantitation of bacterial endotoxin in injectable drugs or solutions for (b) (4) administration and other biological products. In SOP-001186, in attachment A under section "5. DATA REVIEW", the document describes that after analysis, the laboratory notebook, electronic data, and the audit trail must be reviewed by a secondary analyst. In section 5.1.1, the steps specifically document how to perform the check of the (b) (4) Audit Trail. When reviewing the audit trail associated laboratory event #PR 266255, involving (b) (4) Batch (b) (4) which was used to manufacture product, (b) (4), Batch (b) (4), and product, (b) (4) Batch (b) (4), there was no secondary analyst time stamp indicated in the audit trail. The last time stamp logged on the audit trail was from the primary analyst who performed the testing and then subsequent data reprocessing. Furthermore, a lead Microbiologist confirmed that if the SOP was followed correctly, the audit trail would stamp a second analyst time stamp.

B. SOP-000974 "Data Integrity for Quality Control" serves as a policy document and describes the views and practices of the QC laboratory regarding data integrity. Section 2.3 describes the requirement for reprocessing electronic data. In section 2.3.3, it states specifically that supervisor/manager signature, authorizing the stated changes, must be obtained prior to data reprocessing. While reviewing notebook, NB25018-02 p. 60, which contains the raw data involving (b) (4) Batch (b) (4) testing which was used to manufacture product (b) (4), Batch (b) (4), and product, (b) (4) Batch (b) (4) there was no supervisory signature documented in the footnote identifying that the data was reprocessed.

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QUALITY SYSTEM

OBSERVATION 8

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

1) SOP-000974 "Data Integrity for Quality Control, Rev. 3" Attachment 2, provides a general overview only, of your audit trail procedure which governs all audit trail enabled equipment.

On 06/17/2026 during discussion with your QC Compliance Scientist of said audit trail protocol for HPLC (b) (4) (NDA (b) (4)) data, it was determined there is no procedure utilized that ensures software specific review is conducted nor that audit trails are conducted in a repeatable manner. SOP-000974 was the only procedure noted as being utilized to conduct said audit trails. Furthermore:

A. On 6/16/2026, during discussion of "(b) (4) Bacterial Endotoxin Test: (b) (4) Method", one of your lead microbiologists stated that there were two avenues in which the audit trail for the (b) (4) could be accessed. One way, detailed by the procedure, SOP-001186 "(b) (4) Bacterial Endotoxin Test: (b) (4) Method", revision 22, which when followed, records a time stamp for accessing the audit trail,

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with name and date of the user. The analyst explained there was an additional way the audit trail could be accessed, which gave read-only access, and did not provide a time stamp and no trail of date or name of user. The lack of access controls to the audit trail undermines the ability to reconstruct the full course of events related to electronic data review.

B. On 6/16/2026, during review of Laboratory Event PR #266255 "(b) (4) Batch (b) (4) Data Reprocessing" which was used to manufacture product, (b) (4), Batch (b) (4) and product, (b) (4), Batch (b) (4) audit trail and Laboratory Event PR #289263 "Data Reprocessing for endotoxin testing session: Inadvertently added three negative controls" audit trail, there was no secondary analyst time stamp (no user name nor date), which would document the review of the data reprocessing changes made as indicated in SOP-000974 "Data Integrity for Quality Control", Section 2.3.3.

2) SOP-000974 "Data Integrity for Quality Control, Rev. 3" Attachment 1, section 7.5. "Guidelines for (b) (4) " addresses the use of (b) (4) when processing chromatographic data however there is no specificity which outlines practices and review to prevent the manipulation of raw data with (b) (4) .

3) There is no policy or procedure which governs the periodic review of your meta-data to ensure the validity and accuracy of your data is maintained over the entire data life cycle.

4) On 06/15/2026, during discussion of your (b) (4) chromatography data, your QC Compliance Scientist stated that there is no procedure which outlines the periodic review of the "message center" in (b) (4) . The (b) (4) message center is a centralized troubleshooting and monitoring tool that tracks system events, instrument errors and processing failures. Periodic review of this software feature is critical to ensure the equipment and ultimately data, is true and accurate.

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6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon), 6/16/2026(Tue), 6/17/2026(Wed)

X BRYAN L. MCGUCKIN -S Digitally signed by BRYAN L. MCGUCKIN -S Date: 2026.06.17 16:06:56 -07'00'

X Homero W. Aguilar -S Digitally signed by Homero W. Aguilar -S Date: 2026.06.17 16:07:43 -07'00'

X Walden H. Lee -S Digitally signed by Walden H. Lee -S Date: 2026.06.17 16:08:38 -07'00'

X ANNEY LIN -S Digitally signed by ANNEY LIN -S Date: 2026.06.17 16:09:37 -07'00'

X TAREQ W. HADDAD -S Digitally signed by TAREQ W. HADDAD -S Date: 2026.06.17 16:10:13 -07'00'

X Cecilia H. Kieu -S Digitally signed by Cecilia H. Kieu -S Date: 2026.06.17 16:10:46 -07'00'

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."