DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	3/23/2026-3/27/2026
	FEI NUMBER 3000204079

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Harinder S. Kalkat, COO

FIRM NAME	STREET ADDRESS
Allure Labs, LLC	30901 Wiegman Ct
CITY, STATE, ZIP CODE, COUNTRY Hayward, CA 94544-7809	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Investigation of OOS result is inadequate. No root cause or probable root cause was identified. Your firm changed release acceptance/specification without re-validation of the manufacturing process and release drug products to commerce.

Investigation for A/OOS/QC/2024/003 was initiated 11/11/2024 regarding OOS results for product (b) (4) for (b) (4) (b) (4), Batch # (b) (4). The (b) (4) failed at 72,000 (b) (4) (specification is (b) (4) No root cause or probable root cause was identified. You change the (b) (4) release acceptance/specification to a minimum of (b) (4) without scientific justification or re-validation of the manufacturing process. Batch No. (b) (4) (Mfg. Date (b) (4), Exp. Date (b) (4)) in total (b) (4) units were released to the commerce.

LABORATORY SYSTEM

OBSERVATION 2

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nathan E Hellman, Investigator	X Nathan E Hellman Investigator Signed By: 2004157103 Date Signed: 03-27-2026 13:57:14	3/27/2026

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Specifically,

You failed to perform audit trail review of your electronic records to ensure changes, deletions, or modifications did not occur. For example,

A) (b) (4) and the (b) (4) software are used to detect microbial growth in raw material and finished product. Your firm has been using this system since September 2025. SOPMI-23, Operation and Management of the (b) (4) System for Microbial Control Evaluation, section 5.7 states the (b) (4) has audit trail capacity. However, the SOP lacks requirement for audit trail review. No audit trails have been reviewed.

B) HPLC and its associated (b) (4) Software system are used to perform purity assay for APIs and finished products. You have been using this system since end of April 2024, SOPQC-42, Data Integrity, section 5.8 requires the review of audit trails. However, no audit trails have been reviewed.

C) Your firm's QC Manager (b) (6), (b) (7)(C) has two HPLC (b) (4) user accounts, one as "system", and the other as "(b) (6), (b) (7)(C) " with administrator privileges. According to your firm, the "highly sensitive operation" of removing audit trail archive can only be performed by (b) (4) different system administrators. You lack assurance that the (b) (4) audit trail archive is not deleted or removed.

This is a repeat observation from 2021.

OBSERVATION 3

The accuracy of test methods have not been established.

Specifically,

Your firm's test method for microbial release of OTC non-sterile drug product is inadequate. You use the commercially available (b) (4) system to detect total aerobic microbial count (TAMC), total yeast & mold count (TYMC), and objectionable organisms release testing for your OTC non-sterile drug products. Only 9 out of (b) (4) non-sterile drug products were validated using the (b) (4) system also, known as the (b) (4) (b) (4) . Review of the (b) (4) method validation revealed it to be inadequate.

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Additionally, you failed to establish that the (b) (4) method is equivalent to the USP Compendial method. Your non-sterile drug products have the release specification of TAMC: (b) (4), TYMC: (b) (4), and free of objectionable microorganism. However, the (b) (4) method only provides a qualitative result of "Positive" or "Negative" for microbial growth. Also, the (b) (4) method does not have the capability for speciation of objectionable organisms. A total of (b) (4) batches were released into commerce using this method. Without adequate method validation, you lack assurance that your OTC non-sterile drug products meet microbial requirements.

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EMPLOYEE(S) SIGNATURE

Nathan E Hellman, Investigator

X Nathan E Hellman
Investigator
Signed By: 2004157103
Date Signed: 03-27-2026
13:57:14

DATE ISSUED

3/27/2026

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."