DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	11/5/2025-11/10/2025* FEI NUMBER 3034654861

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John F. Reid, President

FIRM NAME	STREET ADDRESS
Dualams, Inc.	8600 Freeport Pkwy Ste 425
CITY, STATE, ZIP CODE, COUNTRY Irving, TX 75063	TYPE ESTABLISHMENT INSPECTED Specification Developer and Complaint File Establishment

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm's procedure Corrective and Preventative Action, AK-SOP-11, Version V.1.0.0, effective 04/05/2024, "applies to all Corrective Action / Preventative Action (CAPAs) initiated by Company." The procedure also defines corrective actions as "all causes of nonconformities relating to product, process, equipment, and quality system discovered during sale, production, post-sale, and/or during quality audits."

However, during review of CAPA files your Quality Manager stated the firm has not had any CAPAs but has had corrective actions as a result of internal audits. The corrective action documentation did not include investigation, root cause analysis, action plan, or effectiveness verification as required by your firm's procedure Corrective and Preventative Action, AK-SOP-11.

OBSERVATION 2

Individuals who conduct quality audits have direct responsibility for the matters being audited.

Specifically, you did not follow your firm's procedure Internal Audit, AK-SOP-22, Version V.1.0.0,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Yuliana Hernandez-Magana, Investigator	X Yuliana Hernandez-Magana Investigator Signed By: YULIANA HERNANDEZ-MAGANA -S Date Signed: 11-10-2025 10:12:53	11/10/2025

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effective 04/05/2024, "RA/QA ensures audit resources have appropriate training to conduct internal audits and impartiality over process(es) being audited. Auditors shall not audit their own work." However, upon review of your Internal Audit Log it was observed your Quality Manager audited the Quality Management System. The Quality Manager has direct responsibility for these areas.

OBSERVATION 3

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

Specifically, your firm has failed to follow your procedure Supplier Evaluation, AK-SOP-05, Version V.1.0.0, effective 04/05/2024, by not completing an Approved Supplier List (ASL), Supplier Survey Form, or Supplier Assessment Form for critical suppliers.

***DATES OF INSPECTION**

11/05/2025(Wed), 11/06/2025(Thu), 11/07/2025(Fri), 11/10/2025(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

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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."