DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	7/28/2025-8/8/2025* FEI NUMBER 3011152407

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Douglas F. Cammann, Vice President of Operations

FIRM NAME	STREET ADDRESS
AnazaoHealth Corporation	7465 W Sunset Rd Ste 1200
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Las Vegas, NV 89113-1944	Outsourcing Facility

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:

OBSERVATION 1

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A. Your firm's process validation for the pellet products intended for implantation does not assess pellet-to-pellet content uniformity. According to Process Validation for Testosterone 12.5 mg Pellet ((b) (4)), Document Number: VAL 097, dated 3/7/2018, Process Validation for Estradiol 6 mg Pellet ((b) (4)), Document Number: VAL 101, dated 7/25/2018, and Analysis of Testosterone, Estradiol, or Naltrexone by HPLC (cGMP, Release Testing), Document Number AMI-1319, at each stage of production - (b) (4) - your firm pooled (b) (4) pellets of either Testosterone 12.5 mg or Estradiol 6 mg for testing, which yielded passing results. However, no individual pellet was tested to assess uniformity, thereby failing to demonstrate content consistency across individual units. Your firm produced approximately (b) (4) pellet batches per (b) (4).

B. Your firm has not established compression speed as a controlled process parameter and has not evaluated its potential impact on pellet quality during production. Compression speed may directly affect pellet weight uniformity, height consistency, and dissolution characteristics but has not been validated or included in your process control strategy. Your firm has recently reported six dissolution failures for estradiol pellets; the investigation into these failures remains ongoing.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Taichun Qin, Investigator	X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 08-08-2025 14:37:35	8/8/2025

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OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. During aseptic operations, the innermost sterile packaging layer of stoppers was routinely briefly exposed to the ISO 7 environment prior to transfer into the ISO 5 Laminar Airflow Hood (LAFH), without disinfection. For example, the camera footage shows that during the production of Ascorbic Acid 30 mL (PF-Non-Corn), Lot # 1021502, Manufactured Date: (b) (4), the (b) (4) outer layers of the stopper packaging were cut open by an operator in the ISO 7 buffer room, and the operator working at the ISO 5 LAFH then extended his gloved hands outside the hood to pull the inner layer directly from the ISO 7 area into the ISO 5 area, exposing the inner layer to the ISO 7 environment. Your firm produced approximately (b) (4) sterile batches of vial products per (b) (4).

B. Your firm has not conducted a hold time study to support the (b) (4) expiration period assigned to depyrogenized glassware and utensils used in the ISO 5 aseptic processing area. Specifically, forceps used to manually place stoppers into vials, scissors used to cut open sterile bags, and beakers used to hold bulk product during batch processing are stored in the ISO 7 area for up to (b) (4) post-depyrogenation without data demonstrating maintenance of sterility or depyrogenation status. These utensils and glassware were wrapped in (b) (4) without being fully sealed.

C. Your firm has assigned a (b) (4) hold time for in-house depyrogenized forceps and a (b) (4) hold time for in-house sterilized stoppers; however, the media fill studies failed to routinely incorporate the maximum hold times for these supplies used in the aseptic processing of vial products, despite a single media fill for 5 mL vials (Document # AHCLV-MBR-0190, dated 5/7/25) inadvertently testing stoppers

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at (b) (4) when expired stoppers were accidentally used and a deviation was reported. The remaining media fills conducted in Cleanrooms (b) (4) and (b) (4) utilized stoppers at less than the maximum (b) (4) hold time.

OBSERVATION 3

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically,

Your firm's complaint investigation procedures are inadequate as investigations consistently fail to include retain sample testing when quality-related adverse events are reported. For example:

A. A provider reported multiple complaints potentially related to insertion site infections, including tenderness, pain, swelling, and/or inflammation after using Testosterone pellets at various dosages in 2025. Your firm's investigation concluded that no deficiencies were identified for these complaints; however, no retain sample testing was performed to evaluate potential sterility, bioburden, or other quality attributes that could contribute to infection reactions.

B. A provider reported that three patients experienced burning sensations following administration of Ascorbic Acid (Preserved) 500mg/mL, Lot 740667 in 2025. Your firm's investigation concluded that no deficiencies were identified; however, returned samples were not tested for critical quality attributes such as pH, assay, related substances, or other parameters that could cause the reported adverse reactions.

OBSERVATION 4

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

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Specifically,

A. Your firm does not test individual pellets for content uniformity during batch release of pellet product. Instead, your firm pools (b) (4) pellets from each batch for routine assay testing. For example, the batch record for Estradiol 10 mg pellet ((b) (4)), Lot# 896276, manufactured on (b) (4) and the batch record of Testosterone 100 mg, Lot# 972948, manufactured on (b) (4) showed that the assay testing performed by a third-party laboratory yielded passing results in accordance with TEST AMI-1319, based on a (b) (4) of (b) (4) pellets. This practice does not evaluate the variability between individual dosage units and cannot ensure uniformity of strength as required by finished products specifications.

B. Your firm does not perform hardness testing for pellet drug products during batch release testing to ensure mechanical integrity and consistent quality of each lot produced. For example, the batch record for Estradiol 10 mg pellet ((b) (4)), Lot# 896276, manufactured on (b) (4), was released without any evaluation of pellet hardness.

***DATES OF INSPECTION**

7/28/2025(Mon), 7/29/2025(Tue), 7/30/2025(Wed), 7/31/2025(Thu), 8/01/2025(Fri), 8/04/2025(Mon), 8/05/2025(Tue), 8/06/2025(Wed), 8/07/2025(Thu), 8/08/2025(Fri)

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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."