DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda CA 94502-7070 510-337-6700 Industry Information: www.fda.gov/oc/industry	09/09 - 09/23/2024* FEI NUMBER 3011152407

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Kimberly C. Kieffer, Director of Quality Assurance

FIRM NAME	STREET ADDRESS
AnazaoHealth Corporation	7465 West Sunset Road, Suite 1200
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Las Vegas, Nevada 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) (WE) OBSERVED:

Observation 1

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. On April 12, 2024, your control testing laboratory analyzed the potency of riboflavin in your human sterile drug product PlenishIV Nutrient Cocktail lot #(b)(4) and found that the chromatogram of the sample "showed different peaks" than the standard chromatogram, resulting in superpotent results of 130.2%. The control testing laboratory did not investigate this out of specification event, but instead obtained a new "standard" from your firm and reperformed analysis with this new "standard" to obtain results within specifications. Your firm relied on these new results to approve the release and distribution of this drug product lot.

B. On April 18, 2024, your control testing laboratory obtained subpotent Pyridoxine HCl results for three lots of your human sterile drug product PlenishIV Nutrient Cocktail (lots (b)(4) , and (b)(4)). The control testing appeared to perform a preliminary investigation and reported their conclusion to your firm on April 22, 2024, that the OOS root cause was an analyst preparing the samples incorrectly but did not provide a scientific rationale to support this conclusion. On April 30, 2024, the control testing laboratory obtained results within specifications from newly prepared samples, and confirmed the OOS results from the original samples. Your firm relied on the new results to invalidate the original results and approve the release and distribution of these three human drug product lots.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Kenneth O. Gee Investigator	09/23/2024

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Observation 2

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

Your firm has not ensured that the glass insert in the container closure system of your implantable pellets remains integral throughout shipment and storage of these sterile human drug products. Between October 31, 2022 and June 19, 2024, your firm received 8 complaints related to glass fragments found inside the pellet container closure system from the broken vial inserts. Glass fragments introduce potential risks to patients if the glass contamination is undetected.

Observation 3

The containers of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(B).

Specifically, your containers do not include the following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1–800–FDA–1088.

Examples of your container labels that do not contain this information:
- Testosterone 75 mg/Anastrazole 4 mg pellet
- Testosterone 87.5 mg pellet
- Testosterone 50 mg pellet

*DATES OF INSPECTION
09/09/2024 (Mon), 09/10/2024 (Tue), 09/11/2024 (Wed), 09/12/2024 (Thu), 09/13/2024 (Fri), 09/16/2024 (Mon), 09/17/2024 (Tue), 09/18/2024 (Wed), 09/19/2024 (Thu), 09/20/2024 (Fri), 09/23/2024 (Mon)

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	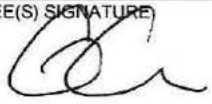	Kenneth O. Gee, Investigator	09/23/2024

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 judgement, 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."