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	7/6-8, 11-15, 28-29/2022
	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 W Sunset Road, Suite 1200
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Las Vegas, NV 89113	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:

QUALITY SYSTEM

Observation 1

The quality unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, the firm has not been reviewing sterility test data packets from their contract testing laboratory for all drug products produced as part of their batch release process for the (b) (4) Suite since January 20, 2015 and for the (b) (4) Suite built in August 2020. Examples of drug products produced in these areas include, but are not limited to (b) (4) Nutrient Cocktail Injection 50mL in Clean Rooms (CRs) (b) (4) Thiamine HCl/Pyridoxine HCl 20/100mg/mL Injection 30mL in CRs (b) (4) and Testosterone Cypionate 200mg/mL Injection 5mL, 10mL and 30mL in CR(b)(4)

PRODUCTION SYSTEM

Observation 2

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, during the validations of your Testosterone 200 mg and Estradiol 6 mg implantable pellets, your firm's sampling plan did not include a sufficient number of samples during potency testing to provide statistical confidence of quality within a batch and between batches. Further, your firm has not demonstrated in these validations that your products safely deliver a constant rate of these hormones over an extended period of time,

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	John A Gonzalez	John A Gonzalez/Investigator	7/29/2022

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instead of having immediate release characteristics. Between November 18, 2019 and March 31, 2022, your firm received approximately 26 reports of adverse events related to your Testosterone and Estradiol implantable pellets, including reports of death, heart attack, stroke, embolism, and breast cancer.

Observation 3

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,
A) your firm received approximately 26 reports of adverse events related to your Testosterone and Estradiol implantable pellets, including reports of death, heart attack, stroke, and breast cancer. However, your firm's investigations into these complaints did not include consideration of additional testing to determine whether these finished drug products have the strength and quality that they purport or are represented to possess. Additionally, 24 out of 26 of these complaint investigations did not include the findings of the investigations, specifically your firm's determination about whether your drug products may have caused or contributed to these adverse events.

B) sterility failure identified by Event 2022-0788 during production of (b) (4) Nutrient Cocktail, Batch (b) (4), 50 mL vials, using (b) (4) as per (b) (4) (b) (4) Received Date 5/13/2022 has not been completed in a timely manner and is under investigation. This investigation must assess the hazards of the aseptic filling operation and determine whether other batches produced on the same production line were affected.

LABORATORY CONTROL SYSTEM

Observation 4

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established and documented.

Specifically, on May 19, 2022, your contract testing laboratory detected visual turbidity in the sterility testing

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(b) (4) for your (b) (4) Nutrient Cocktail lot (b) (4), and confirmed that this turbidity was caused by microbial contamination with Staphylococcus epidermidis. However, your contract testing laboratory failed to detect this microbial contamination in lot (b) (4) using the (b) (4) method, which indicates that this rapid microbiological test method may be unsuitable for performing sterility testing on your drug products. The (b) (4) test method was also used to perform sterility testing on approximately (b) (4) lots of the following drug products between July 1, 2021 and July 1, 2022:

1. (b) (4)
2. Ascorbic Acid (PF/Non-Corn) 500mg/mL
3. Ascorbic Acid (PRESERVED/Non-Corn) 500 mg/mL
4. B-COMPLEX
5. B-NICOTINAMIDE ADENINE DINUCLEOTIDE 125 mg/mL
6. COMPOUNDED (b) (4) 50 MG/ML
7. COMPOUNDED (b) (4) 50 MG/ML
8. EDETATE DISODIUM (PF) 150mg/mL
9. GLUTATHIONE (PF) 200 MG/ML
10. GLUTATHIONE (PRESERVED) 200 mg/mL
11. L-CARNITINE 500 MG/ML
12. LIPOIC ACID 25 mg/mL
13. LYSINE HCL 100 mg/mL
14. METHIONINE/INOSITOL/CHOLINE 25/50/50 MG/ML
15. METHYLCOBALAMIN 10,000 MCG/ML
16. METHYLCOBALAMIN 5,000 MCG/ML
17. MIC W/CYANOCOBALAMIN 25/50/50/1 MG/ML
18. (b) (4) Nutrient Cocktail
19. THIAMINE HCL 20 MG/PYRIDOXINE HCL 100 MG/ML

FACILITIES AND EQUIPMENT SYSTEM

Observation 5

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Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm stores equipment with difficult to clean surfaces inside the ISO 7 areas surrounding the ISO 5 aseptic processing areas, such as surfaces that are porous, particle-generating, or visibly dirty. Examples include the following:

A) a clear plastic storage bin in the ISO 7 area of Clean Room (b)(4) with a (b) (4) sticker on the outside; larger plastic storage bins with (b) (4) (b) (4) ; and a (b) (4) trash can.

B) a stepstool that is stored under Biological Safety Cabinet (BSC) (b)(4) in ISO 7 area of Clean Room (b)(4) with various stickers and a chair used by (b) (4) with sticker on the back. I also observed stains on the (b) (4) used during mixing in BSC (b)(4)

C) cracked front shields (sashes) on (b) (4) Hoods ((b)(4)) (b) (4) in ISO 7 area of CR used to (b) (4) for further (b) (4) . The firm does not know when these cracks occurred and any negative effects on its products.

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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 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."

USFDA
7/29/2022
JAG