DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
San Francisco District 1431 Harbor Bay Pkwy Alameda, CA 94502 (510) 337-6700 Industry Information: www.fda.gov/oc/industry	3/15/2017 - 3/24/2017
	FEI NUMBER 3011152407

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Hal J. Weaver, President

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

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, during the (b) (4) re-qualification of your (b) (4), your firm failed to maintain your sterilizing and depyrogenation (b) (4) established in your protocol for (b) (4) and depyrogenation. For example, the following criteria established in your protocols were not met during the (b) (4) re-qualification:

A. November 2016 (b) (4) Depyrogenation for 5mL glass vials (b) (4) None of the (b) (4) to ensure adequate depyrogenation.

B . November 2016 (b) (4) drug solution (b) (4) – The (b) (4) criteria established by your firm was not met by (b) (4) used to ensure (b) (4) within the (b) (4) for the (b) (4) of oil based injectable drug products including Testosterone Cypionate 200mg/mL.

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Your firm lacks scientific justification for using (b) (4) Sterilization Validation method for sterilization of compounded pellet products which includes but are not limited to Testosterone, Testosterone/Anastrozole, and

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Estradiol products.

Your firm follows methods in ISO 11737 that consists of the following parts entitled (b) (4) (b) (4). Your firm lacks sufficient scientific justification to show this validation method is specific for your pharmaceutical pellet products.

Sterile pellet drug product batches produced for (b) (4) are not representative of the routine manufacturing batches. Your firm produces approximately (b) (4); however, your firm's routine manufacturing batches may produce up to (b) (4).

OBSERVATION 3

Drug products failing to meet established specifications and quality control criteria are not rejected.

Specifically,

A. On 3/16/2017, we observed Pharmacy Technician (b) (6) performing visual inspection of sterile injectable drug product, MIC with Cyanocobalamin 25/50/50/1mg per mL, 30mL vials, lot #031417-1KS-151641. (b) (6) performed visual inspection for approximately 1.5 hours without taking any breaks. After these vials passed visual inspection, we reviewed 9 vials from the lot and observed 2 vials appeared to have particles or specs adhering to the inside of the glassware. This defect was confirmed by your firm's Sterile Supervisor (b) (6) and (b) (6) stated these vials should have been rejected per your firm's visual inspection SOP.

In addition, we inspected Testosterone Cypionate 200mg/mL, lot #031017-2KS-151385, which had completed visual inspection. We observed particles in 4 vials out of the 25 we reviewed. These particles were confirmed by Sterile Supervisor (b) (6) and Pharmacy Technician (b) (6) According to Sterile Supervisor (b) (6) these vials should have been rejected per your firm's visual inspection SOP.

B. On 03/20/2017, we inspected MIC with Cyanocobalamin 25/50/50/ 1mg per mL, 4 ml Injectable, lot

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#030917-1JH-151291. This lot size consisted of (b) (4) We inspected the lot after it passed the 100% visual inspection and we observed 20 vials with seal damage. Sterile Supervisor (b) (6) confirmed the seal defects and stated the vials should have been rejected per your firm's visual inspection SOP.

OBSERVATION 4

Employees engaged in the processing of a drug product lack the training required to perform their assigned functions.

Specifically, Our review of your firm's visual inspection (b) (4) revealed the (b) (4) does not reflect actual vials encountered during the visual inspection process. For example, the (b) (4) does not include a representative vial with a pink colored solution in an amber colored vial similar to what is observed in MIC with Cyanocobalamin injectable products and Methylcobalamin injectable products. We also observed particles in test vials #2, 17, 23, and 52 which were labeled as controls (without particles or defects). We reviewed the visual inspection (b) (4) results and found while some technicians were able to identify the same particles, others did not, indicating the technicians are not properly trained and fully qualified to perform visual inspection. The (b) (4) also includes (b) (4) such as (b) (4) (b) (4)

OBSERVATION 5

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically, we reviewed the alarm settings and temperature recording for (b) (4) incubators and (b) (4) (b) (4) on 3/22/2017 and observed the following deficiencies:

A. Your firm has not set high and low alarms for the temperature of your firm's Incubator (b) (4) The incubator is used to incubate environmental monitoring samples from (b) (4). We reviewed the temperature

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recordings for the previous year and observed on numerous occasions the incubator dropped below the (b) (4) lower limit including on 11/15/2016 when the temperature was out of range for more than 10 hours during the incubation of environmental monitoring samples. Your firm has not investigated these events to ensure the samples in the incubator are not affected.

B. Your firm's alarm settings for (b) (4) are not configured to notify you when the temperature drops (b) (4) The (b) (4) is used to store environmental monitoring samples that are required to be incubated at (b) (4). We reviewed the temperature measurements for the previous year and observed on numerous occasions the temperature in the (b) (4) dipped below (b) (4) during the incubation of environmental monitoring samples. For example, between 10/25/2016 and 11/29/2016, the temperature recorded at this location was below (b) (4) the entire time period. Your firm has not investigated these events to ensure the samples in the (b) (4) are not affected.

In addition, your firm failed to provide documentation regarding investigations into multiple out of specification results for potency of your Estradiol 6mg pellets and Testosterone 25mg pellets from April 2016. We requested to review OOS #113, 119, and 121 investigations and were informed these investigations could not be located.

OBSERVATION 6

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

On (b) (4) we observed media fill batch (b) (4) on a metal shelf in the hallway outside ante room (b) (4) (b) (4). There is no temperature probe physically close to this area and no documented temperature monitoring of this hallway. Your firm does not have data to determine whether or not the media fill batch was incubated at the appropriate (b) (4) temperature requirement for (b) (4)

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OBSERVATION 7

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not review the pressure differential data to ensure there were no unacceptable losses of pressure obtained during manufacturing operations in your cleanrooms. Your firm only reviews alarms however your (b) (4) system is set to only (b) (4) Your firm does not have any justification for choosing (b) (4) as your criteria for (b) (4)

OBSERVATION 8

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically, your firm's technicians wear sterile goggles for (b) (4) prior to discarding the goggles. These goggles are sanitized with (b) (4). However, your firm failed to properly validate the cleanroom goggle sanitization process. Cleanroom Goggles Sterilization Validation VAL 033 is inadequate in that (b) (4) samples collected were not transported to the testing laboratory within the required time frame. (b) (4) Validation samples from weeks 2 and 3 did not reach the testing laboratory within the required time frame. However, your firm accepted the results and established your cleanroom goggle sanitization time periods based on these invalid test results.

OBSERVATION 9

Bulk drug substances used by your outsourcing facility to compound drug products are not each manufactured by an establishment that is registered under section 510 as required by section 503B(a)(2)(C).

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Specifically,

On 03/21/2017, the following bulk drug substance manufacturer was identified as not being registered with the FDA:

(b) (4)

The inositol raw ingredient is used in the production of the following finished products:

- Methionine/Inositol/Choline (MIC) 25/50/50 mg/ml 30ml
- MIC with Cyanocobalamin 25/50/50/1 mg/ml 30 ml
- MIC with Cyanocobalamin 25/50/50/1 mg/ml 4 ml

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