DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 Industry Information: www.fda.gov/oc/industry	7/12/2021-7/23/2021
	FEI NUMBER 3015134033

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eghomware J. Igbinovia, Owner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
ACRX Specialty Pharmacy Inc	3200 Soaring Gulls Dr Ste 101
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Las Vegas, NV 89129-2198	Producer of Sterile and Non Sterile Drug Products

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
The ISO 5 classified aseptic processing areas had difficult to clean and visibly dirty equipment or surface.

Specifically,

It was observed that the ISO 5 classified aseptic processing areas contained difficult to clean and visibly dirty surfaces and that Pharmacist-in-Charge (PIC) did not clean them before and after producing Glutathione (BUD MDV) 200 mg/ml Inject Soln, Lot #07122021@8 on 7/12/2021 for the following:

A. The HEPA filter cover positioned above the work surface inside the ISO 5 LAFH contained brownish stains on its surface.

B. The frames of the HEPA filter and its joints with the ISO 5 LAFH contained brownish stains.

C. There was a gap between a stainless-steel bar pot rack with hooks used to hold sterile bags or devices and the holder at its joint with the ISO 5 LAFH on both sides, which was difficult to clean.

D. The red IVA seals holder hung on a bar pot rack inside the ISO5 LAFH. The IVA seals must be removed in order to clean the holder thoroughly.

E. Unknown stains were observed in a hard-to-reach area under a row of light bulbs of the LAFH and near the HEPA filter.

OBSERVATION 2
Non-microbial contamination was observed in your production area.

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	Taichun Qin	Taichun Qin, Investigator	7/23/2021

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Specifically,

A. A dusty filth-like material was present on the back side of a (b) (4) hood (b) (4) used to produce non-sterile products and to weigh ingredients used to produce sterile products. Also, unknown powders were presented at the corner of the working surface after the hood has been cleaned for weighing ingredients used for producing Glutathione (BUD MDV) 200 mg/ml Inject Soln, Lot #07122021@8 on 7/12/2021.

B. Unknown stains were widely distributed on the interior surface of the front window of a (b) (4) hood ((b) (4)) used to produce non-sterile products.

C. Unknown rust-like stains were observed on a metal wheel of the ISO 5 LAFH located in the ISO 7 cleanroom.

D. A small ball of cotton-like substance and unknown brownish dirt stuck to a cart used to store various materials for sterile compounding in the ISO 7 cleanroom.

OBSERVATION 3
Your firm produced drug products with materials that had not been verified to assure that they did not contribute to endotoxin contamination that may be objectionable given the product's intended use.

Specifically,

You used Glutathione (b) (4), dietary supplement to produce Glutathione (BUD MDV) 200 Mg/Ml Inject Soln. For example, you purchased Glutathione (b) (4), lot # (b) (4), dietary supplement from (b) (4) on 11/18/2020 and used this ingredient to produce Glutathione (BUD MDV) 200 Mg/Ml Inject Soln, Lot # 05102021@12 on 5/10/2021. During the period of April to June 2021, you produced Glutathione (BUD MDV) 200 Mg/Ml Inject Soln for 9 prescription orders: Rx (b) (6) Rx(b) (6), Rx(b) (6) Rx(b) (6), Rx(b) (6), Rx(b) (6), R(b) (6), Rx(b) (6) and Rx(b) (6); however, you have not verified that Glutathione (b) (4), dietary supplement did not contribute to endotoxin contamination for every batch you produced and within its Beyond Use Date, which is 183 days after the compounding date.

OBSERVATION 4

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Dynamic smoke studies are not representative of production.

Specifically,

It was observed that during aseptic processing, a sterile bag containing (b) (4) hung on a hook inside the ISO 5 LAFH swung back and forth for over a minute immediately after PIC released the bag, which he held at approximately a 45-degree angle to draw (b) (4) from a port of the bag, but the video of smoke study conducted 3/1/2021 showed a sterile bag hung on the hook was static.

OBSERVATION 5
Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically,

It was observed that a sterile bag containing (b) (4) hung on a hook inside the (b) (4) ISO 5 LAFH swung back and forth for over a minute every time after PIC used a sterile syringe to draw (b) (4) from a port of the bag to dissolve bulk drug substances or other ingredients during aseptic processing of Glutathione (BUD MDV) 200 mg/ml Inject Soln, Lot #07122021@8 on 7/12/2021. Your sterile vial sealed with stopper, opened sterile wipes, and syringes with exposed needles were placed under or near the bag. Also, you (b) (4) into a sterile vial approximately a foot apart from the bag inside the ISO5 LAFH.

OBSERVATION 6
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically,

Each (b) (4) ingredient in a non-sterile plastic weighing boat used to produce a sterile drug product was weighed inside the non-sterile (b) (4) hood (b) (4)). It was observed that PIC used a (b) (4) sterile wipe to hold the bottom of the weighing boat and placed on the working surface of the ISO5 LAFH without wiping the entire weighing boat.

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OBSERVATION 7

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically,

Prior to donning gowning apparel, PIC washed his hands and forearms in a sink in the ISO 7 anteroom and then walked to a cart in the room to get wipes to dry his hands and forearms; however, it was observed water was dripping onto the ground from his hands and forearms. The shoe cover that touched the wet spillage had direct contact with the sterile gowning apparel while donning it or it can be brought into the ISO 7 cleanroom.

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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."