DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expressway, #300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	06/25-29/18, 7/2, 5 & 11/18
	FEI NUMBER 3001576820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: David K. Johnson, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
CFP Acquisitions, Inc.	6136 E. 51st St.
CITY, STATE AND ZIP CODE Tulsa, OK 74135	TYPE OF ESTABLISHMENT INSPECTED Producer of 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

Personnel engaged in aseptic processing were observed with exposed skin around the face and with their face and exposed skin inside of the ISO 5 hood. Personnel did not disinfect gloves to prevent contamination.

Specifically,

a) On 6/26/18 and 6/27/18, I observed your technician preparing sterile drug preparations in an ISO 5 laminar flow hood with exposed skin around the face (forehead, eyes and side of cheeks).

b) On 6/26/18 and 6/27/18, I noted that your technician did not sanitize the second pair of sterile gloves after donning.

Lot #06262018@1 of Tri-Mix 15/0.5mg/5mcg/mL was made on 6/26/18. Lot #s 06272018@5 of Papaverine/ Phentolamine 30/1mg/mL, #06272018@6 of Tri-Mix 18/1/10, and #06272018@7 of Tri-Mix 30/1/10 were made on 6/27/18.

OBSERVATION 2

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Margaret M. Annes	Margaret M. Annes, CSO	07/11/2018

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Specifically, media fills performed by your firm with each of the operators that work in the ISO 5 area do not closely simulate actual production conditions or cover worst case or most challenging conditions. In routine production, batch sizes can be in excess of (b) (4) units and can involve (b) (4) (b) (4) The media fill your firm performs has the operator (b) (4) (b) (4) and then (b) (4) . This same step is then repeated (b) (4) more times using (b) (4) each time.

This is a repeat observation from the 3/3-13/15 inspection.

OBSERVATION 3

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically, your firm did not have adequate contact time for the (b) (4) ((b) (4) solution) or the (b) (4) for use as a sporicidal. Your technician sprays the solution onto a sterile wipe and then wipes down the surface of the ISO 5 hood, amounting to a contact time (surface being wet) of less than (b) (4) (b) (4)

OBSERVATION 4

Environmental monitoring samples were not performed to ensure recovery of organisms.

Specifically, on 7/2/18, I observed your technician wipe the surface of the ISO 5 laminar flow hood with sterile (b) (4) and after less than (b) (4) minutes, she performed a surface sample of the site.

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OBSERVATION 5

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production.

Specifically, the magnehelic gauges that monitor the pressure differential between the ISO 7 cleanroom (room with ISO 5 laminar flow hoods) and the ISO 8 Ante Room (room where drug products are prepared) and the ISO 8 Ante Room and the unclassified pharmacy area, do not appear to be functioning properly, which may allow influx of poor quality air into a higher classified area. When the door from the unclassified pharmacy to the ISO 8 Ante Room is opened, both gauges show movement. When the door from the ISO 7 cleanroom to the ISO 8 Ante Room is opened, neither gauge moves.

OBSERVATION 6

The ISO 5 classified aseptic processing areas has difficult to clean or particle-generating equipment or surfaces.

Specifically, the (b) (4) hood (ISO 5) located in your ISO 7 Cleanroom, has a cabinet that it is "mounted on a work surface constructed of pressed wood laminated with a (b) (4) ".

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