DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Main Place 1201 Main St., Suite 7200 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	11/10, 12, 15, 17/2021, 12/03, 08, 2021 & 01/18/2022
	FEI NUMBER 3001576820

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Thomas J. Marti, President

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

Your firm released drug product in which the strength differs from that which it purports or is represented to possess.

Specifically, 3rd party testing of Lot #09082021@1 of Methylcobalamin 5000mcg/mL Injectable made on September 8, 2021 found the potency to be 89.3%. The specifications for assay for this product are (b) (4) . Your firm did not reject the product and instead distributed the product to customers, increasing the dose to be administered. The Formula Worksheet for this lot does not document the exact number of vials that were filled. Based on the next lot made, approximately (b) (4) and (b) (4) vials were filled. Your firm has dispensed the entire lot.

OBSERVATION 2

Your cleanrooms are outfitted with HEPA filters directly adjacent to the return vent in the ceiling.

Specifically, your ISO 7 Buffer Room and ISO 8 Ante Room are not designed with low wall air returns or returns near the floor. The air returns are in the ceiling next to the high efficiency particulate arrestance (HEPA) filter. This design does not allow for proper circulation of air and prevents effective dilution of particle-laden air by HEPA filtered air.

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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	01/18/2022

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OBSERVATION 3

There is a lack of routine and rigorous certification of the ISO 5 area, including smoke studies performed under dynamic conditions.

Specifically, your firm has not performed smoke studies in the ISO 5 Laminar Flow Hood (LFH) and ISO 7 Buffer Room under dynamic conditions that simulate actual working conditions since 2018.

OBSERVATION 4

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, your firm uses (b) (4) grade to adjust the pH of several sterile drug products, including (b) (4). Furthermore, your firm did not list this ingredient on the Formula Worksheets when used. Lots that were made and dispensed/distributed include lot #s (b) (4) and (b) (4) of (b) (4).

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OBSERVATION 5

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

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 and/or cover worst case or most challenging conditions for "batch filling" (non-ophthalmic sterile drug products). In routine production, your firm fills sterile drug products into (b) (4) vials and batch sizes can be in excess of (b) (4) units.

The media fill your firm performs has the operator filling (b) (4) vials ((b) (4) fills in (b) (4) vial). Your firm does not include any media fills with (b) (4) vials.

Your firm has no documentation showing the incubation and final read results for the (b) (4) vials that are a (b) (4) fill in a (b) (4) vial. Your firm only documents the incubation and read results for the (b) (4) vials that are a (b) (4) fill in a (b) (4) vial.

This is a repeat observation from the 3/3-13/15 and 6/25-07/11/2018 inspections.

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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."