DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	4/12/2022-5/4/2022* FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Aaron M. Schneider, RPh, Co-Founder/Director of Operations	
FIRM NAME Revive Rx LLC dba Revive Rx Pharmacy	STREET ADDRESS 3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Sterile & Non-Sterile Drug Producer

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 OBSERVED:

Production Control

OBSERVATION 1

Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product

Specifically,

A. On 4/26/2022 aseptic processing visual observations were made of the sterile drug product, (b)(4) Sterile Solution for Injection, Lot # (b)(4) BUD 10/23/2023, your firm pharmacy technician while placing rubber stoppers in finished product filled vials, was observed reaching over open vials. Following our discussion regarding poor aseptic techniques, your firm decided to dispose of this observed sterile lot.

B. On 4/19/2022, while visually observing the aseptic processing of the sterile drug product, (b) (4) , Lot # (b) (4) , BUD 7/31/22, I observed your firm pharmacy technician use poor aseptic techniques in the positioning of the syringe to form the connection with the tubing which inhibited the presence of 1st air when forming the connections between each syringe fill. Following our discussion regarding poor aseptic techniques, your firm decided to dispose of this observed sterile lot.

C. On 4/19/2022, while visually observing the aseptic processing of the sterile drug product, (b) (4) , Lot # (b) (4) , BUD 7/31/22, I observed both your PIC and pharmacy technician failed to disinfect sterile gloves prior to returning and place processing components inside ISO 5 BSC, while placing drug components into and removing trash from the

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator X Camerson E Moore Investigator Signed By: Camerson E Moore - S Date Signed: 05-04-2022 11:06:53	DATE ISSUED 5/4/2022

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BSC during processing of the sterile drug product. Following our discussion regarding poor aseptic techniques, your firm decided to dispose of this observed sterile lot.

Materials Control

OBSERVATION 2

The (b)(4) intended to render final product sterile is not adequate to accomplish (b)(4) and/or is not pharmaceutical grade.

Specifically, your firm fail to use sterile pharmaceutical grade (b)(4) during the processing of sterile drug products. For example, your firm uses a (b)(4), during the aseptic processing of the finished sterile drug product, Dexamethasone 24 mg/ml Sterile Solution pH 7. A review of your firm Production Log, I found 2 Lots produced that remain within expiry, Lot # 585669 (BUD 6/18/2022) and 668512 (BUD 8/15/2022). There have been 6 (six) patient-prescriptions dispensed from the aseptically process lots.

Facilities and Equipment Control

OBSRVATION 3

There is inadequate HEPA filter coverage or airflow over the area to which sterile product is exposed.

Specifically, your firm has (b)(4) Systems in the cleanroom. (b)(4) does not appear to have enough HEPA filters in proper locations to provide adequate coverage to ensure ISO 5 environment is maintained from the ISO 5 BSC used for aseptic processing, to the (b)(4) and from the (b)(4) to the (b)(4) crimping station. **This is a repeat observation.**

OBSRVATION 4

(b)(4) integrity testing to the (b)(4) was not performed.

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Specifically, your firm failed to adequately test and record the results from (b)(4) testing of the Sterile (b)(4) On 4/19/2022 and 4/26/2022, I observed your firm perform a (b)(4) test on the (b)(4) used to render the process drugs, (b) (4) , Lot # (b) (4) , BUD 7/31/22 and (b)(4) Sterile Solution for Injection (Continuation Dose), Lot # (b)(4) 10/23/2023, respectively, by your firm pharmacy technician. She was unable to adequately provide sufficient pressure using a (b)(4) syringe to deliver the (b)(4) , which would test the (b)(4) to the manufacturer's specification. Your firm following our discussion of observed deficiencies disposed of both aseptically processed lots.

OBSERVATION 5
Sinks or drains are present in the cleanroom where the ISO 5 area is located.

Specifically, your firm's (b)(4) system, located approximately (b)(4) feet apart within the ISO 7 Buffer Room/Cleanroom, require water to drained from the unit using a (b)(4) plastic bucket that was in your firm's ISO 8 Ante Room/Gowning at the completion of a cycle. Your firm's (b)(4) are located adjacent to ISO 5 BSC and the ISO 5 LAFU used for aseptic processing and (b)(4) crimping equipment respectively.

OBSERVATION 6
Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, I observed an exposed/unsealed fire sprinkler head within your firm's ISO 8 Ante Room/Gowning, and ISO 7 HD Anteroom/Prep Room, and ISO 7 Buffer Room/Cleanroom along with unsealed ceiling tiles.

OBSERVATION 7
The ISO-classified have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

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Specifically, foreign particulates were observed on the top of the firm's ISO 5 BSC, ISO 5 LAFU and (b)(4) systems located in the ISO 7 Non-Hazardous Buffer Room.

OBSERVATION 8

Cleanroom smoke studies conducted in cleanroom under dynamic conditions are inadequate.

Specifically, your firm's smoke studies conducted as part of your firm August 18, 2021, Cleanroom re-certification is inadequate. For example, your firm's smoke studies failed to include and assess complex intervention(s) within your firm's ISO 5 BSC as part of the unit's recertification process.

OBSERVATION 9

(b)(4) glassware used in the processing of sterile drug product is exposed to less than ISO 5 air quality.

Specifically, your firm failed to ensure (b)(4) glassware used in aseptic processing is not exposed to less than ISO 5 air. For example, on 4/19/2022, your firm was observed using an uncovered glass beaker that had undergone (b)(4), used in the processing of the sterile drug product, (b) (4) vial for injection, Lot # (b) (4), BUD 7/31/22 within your firm's ISO 7 HD Ante Room and ISO 7 Non-Hazardous Buffer Room. The breaker contains the bulk (b)(4) drug product, (b) (4) during mixing of drug components and transfer prior to (b)(4) within the ISO 7 Non-Hazardous Buffer Room.

***DATES OF INSPECTION**

4/12/2022(Tue), 4/13/2022(Wed), 4/14/2022(Thu), 4/15/2022(Fri), 4/18/2022(Mon), 4/19/2022(Tue), 4/20/2022(Wed), 4/21/2022(Thu), 4/22/2022(Fri), 4/25/2022(Mon), 4/26/2022(Tue), 4/27/2022(Wed), 4/28/2022(Thu), 4/29/2022(Fri), 5/02/2022(Mon), 5/03/2022(Tue), 5/04/2022(Wed)

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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 judgment, 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."