DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/9/2026-3/27/2026*
	FEI NUMBER 3016710945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven J. Lynn, Chief Quality Officer

FIRM NAME	STREET ADDRESS
Revive Rx LLC dba Revive Rx Pharmacy	3831 Golf Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Houston, TX 77018-5218	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drugs

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:

OBSERVATION 1

Microbial contamination was present in the ISO 5 area and areas adjacent to production areas.

Specifically,

A. Your environmental monitoring data shows persistent and repeated recovery of microorganisms, including mold and spore-forming bacteria, in both ISO Class 5 and ISO 7 classified areas.

Recoveries in ISO 5 areas:

- **3/5/2025**: 1 CFU Gram-positive rods (not identified) recovered post-batch in Hood (b) (4)
- **4/3/2025**: 1 CFU Gram-positive rods (not identified) recovered post-batch in Hood
- **4/8/2025**: 1 CFU Gram-positive rods (not identified) recovered post-batch in Hood
- **4/8/2025**: 1 CFU Gram-positive rods (not identified) recovered post-batch in Hood
- **4/29/2025**: 1 CFU (not stained, not identified) recovered post-batch in Hood (b) (4)
- **5/12/2025**: 1 CFU (not stained, not identified) recovered post-batch in Hood
- **7/10/2025**: 1 CFU Gram-positive rods identified as *Streptomyces olivaceous* recovered in Hood (b) (4)
- **8/5/2025**: 1 CFU identified as fungus *Penicillium oxalicum* recovered post-batch in Hood (b) (4)
- **8/15/2025**: 1 CFU Gram-positive rods (not identified) recovered in Hood (b) (4)
- **9/8/2025**: 1 CFU identified as fungus *Scolecobasidium dendroides* recovered in Hood (b) (4)

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	Sangeeta M Khurana, Investigator-GDUFA X Sangeeta M Khurana Investigator-GDUFA Signed By: SANGEETA M. KHURANA -S Date Signed: 03-27-2026 10:50:35	3/27/2026

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- **9/10/2025**: 1 CFU identified as fungus *Penicillium citrinum* recovered in Hood (b) (4)
- **1/20/2026**: 2 CFU identified as *Bacillus safensis* recovered in Hood (b) (4)
- **1/26/2026** 1 CFU identified as fungus *Paenibacillus sp* recovered in Hood (b) (4)

Recoveries in ISO 7 areas:

- **10/14/2025: 54 CFU** consisting of *Micrococcus luteus, Staphylococcus hominis, Staphylococcus epidermidis, Mixta calida*, *Aspergillus austroafricanus* / fructus / griseoaurantiacus / protuberus / tabacinus */ versicolor, Dietzia sp.* oral taxon recovered in Anteroom ((b) (4))
- **11/12/2025:** 4 CFU fungus *Hamigera inflata/insecticola* recovered in (b) (4) Prep room
- **11/12/2025:** 2 CFU fungus *Aspergillus hiratsukae / shend aweii* recovered in (b) (4) Prep room.

B. Organism Identification Incomplete: Most of the microbial recoveries (18 of 29 recoveries) are documented as "Not identified," preventing your firm from determining the source of contamination (environmental vs. operator-derived) and implementing appropriate corrective actions.

C. Persistent Contamination: The repeated recovery of microorganisms in the same locations (e.g., multiple recoveries in Hood (b) (4), Hood (b) (4) Anteroom) over a 12-month period indicates that corrective actions, if implemented, have been ineffective.

D. Inadequate cleaning and disinfection: On 6/17/2025, following a breach cleaning of the Anteroom, viable air sampling recovered **10 CFU** consisting of 2 Gram-positive rods and 2 Gram-negative rods (not identified). This elevated recovery immediately following a breach clean which consists of cleaning (b) (4) times with (b) (4) followed by (b) (4) (b) (4) times indicates inadequate cleaning and disinfection.

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E. No Enhanced Monitoring: Following microbial recoveries, your firm does not perform additional environmental monitoring to verify that cleaning and corrective actions have eliminated the source of contamination.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 2
Lack of adequate personnel sampling.

Specifically,

Personnel monitoring for your operators is performed during the (b) (4) gowning qualification. After that personnel monitoring is performed during the (b) (4) gowning competency assessment and (b) (4) media fill qualifications. No routine personnel monitoring is performed upon completion of production batches.

Colonies belonging to human flora were isolated from ISO 5 Hoods during production:

- **Hood** (b) (4) *Streptomyces olivaceous*, during production of Tirzepatide Lot# 12246565 on 7/10/2025
- **Hood** - *Micrococcus luteus* during production of Tirzepatide Lot #s 14031295 and 14162530 on 12/8/25, and 12/18/25.
- **Hood** (b) (4) *Micrococcus luteus* during media fill on 3/24/2025
- **Hood** *Micrococcus luteus* during production of Semaglutide Lot# 14427530 on 1/12/26
- **Hood** *Corynebacterium ureiceler* during production of NAD+ Lot# 12231180 on 7/9/2025.

All the recovered isolates were not identified. However, after Gram staining, the firm categorized rest of the unidentified colonies to be of human origin.

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In addition, the review of the (b) (4) gowning qualification revealed that at least (b) (4) of the operators failed their (b) (4) gowning competency. The (b) (4) gowning qualification also revealed a supervisor failed the gowning competency. Another Supervisor failed (b) (4) media fill qualification.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 3

Smoke studies were not performed under dynamic conditions.

Specifically,

Your firm conducted smoke studies on 2/9/2026 only under static conditions in Hoods (b) (4) and (b) (4) located in positive pressure clean room. These two ISO Class 5 primary engineering controls are used to compound injectable sterile drug products. The review of smoke studies performed in these hoods, in static conditions, showed empty hoods with single stream of smoke introduced towards the HEPA filter face.

Your smoke studies under static conditions only do not provide an assurance that the first air from HEPA filters is maintained over critical sites (e.g. (b) (4) bag filled with compounded drug, (b) (4) tubing, vials, vial stoppers) when operators position their hands and arms in the hood or when equipment and materials are arranged as during actual production, thereby creating conditions whereby sterile drug products may become contaminated.

Since 09/26/2025 your firm has compounded approximately (b) (4) **batches** of sterile drug products in Hood (b) (4) and since 12/26/2025 (b) (4) **batches** in Hood (b) (4) Most of the batches have been dispensed and distributed.

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OBSERVATION 4

Sterile drugs and Materials were exposed to lower than ISO 5 quality air.

Specifically,

Your firm transfers (b) (4) vials filled with drug products intended to be sterile from ISO Class 5 Biological Safety Cabinets (BSCs) through the ISO Class 7 negative pressure cleanroom to (b) (4) During this transfer, the (b) (4) vials, which contain exposed sterile product, are subjected to air quality worse than ISO Class 5.

Your firm also operates (b) (4) and (b) (4) located in the positive pressure cleanroom. (b) (4) vials are similarly transferred from ISO Class 5 hoods through the ISO Class 7 positive pressure cleanroom to these (b) (4), exposing sterile products to worse than ISO Class 5 air quality during this transfer. On 03/09/2026, I observed (b) (4) vials of HCG 12,000 IU Vial Lot # 15120575 Hood (b) (4) to (b) (4) The vials were carried in approximately (b) (4) trays, (b) (4) at a time, (b) (4) trays containing approximately (b) (4) vials and the (b) (4) tray was (b) (4) filled.

Your firm's (b) (4) drug products compounded in negative and positive pressure clean rooms include but are not limited to: Tesamorelin, Human Chorionic Gonadotropin, NAD+, Trimix XL, Hexarelin, Sermorelin, FSH, Ipamorelin, Long R3-IGF, Gonadorelin, and SS-3.

In the previous three months your firm produced (b) (4) **batches** of (b) (4) sterile drug products in the negative pressure room using (b) (4) In the positive pressure clean room in previous three months (b) (4) **batches** of sterile (b) (4) drug products were produced using (b) (4). Most

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of the batches have been dispensed and distributed.

THIS IS A REPEAT OBSERVATION.

OBSERVATION 5

Use of (b) (4) that are not sterilized by routine sterilization cycles and protected from contamination by sterilizing (b) (4) on vacuum break air lines/vents.

Specifically,

On 3/10/26, your Production Manager stated that all of the (b) (4) are cleaned after each production run using (b) (4) with a contact time of (b) (4), followed by (b) (4). (b) (4) sterilization is conducted (b) (4).

Your firm does not use (b) (4) sterilization, (b) (4) sterilization, or any other validated sterilization method to sterilize the interior chambers of the (b) (4) between production runs or on a routine basis.

THIS IS A REPEAT OBSERVATION.

***DATES OF INSPECTION**

3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu), 3/13/2026(Fri), 3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri)

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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."