DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	9/9/2025-9/19/2025* FEI NUMBER 3022250654

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Gregory G. Gaiser, Senior Vice President

FIRM NAME	STREET ADDRESS
ProRx LLC	619 Jeffers Cir
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Exton, PA 19341-2540	Outsourcing Facility

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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm failed to investigate media fill vials with positive microbial growth. Operators (b) (6), (b and (b) (6), (b conducted (b) (4) media fill batches on consecutive days (March24 -26, 2025), with each operator required to fill (b) (4) trays of vials per batch for qualifying operators for aseptic production. On April 8, 2025, positive microbial growth was reported for one vial from the first batch of each operator from the March 24, 2025 media fill batch. No positive growth was reported in the March 25 or the March 26, 2025 media fill batches. Your firm did not investigate the root cause of the positive growth events and did not perform microbial identification of the affected vials. Despite these contamination events, both operators were subsequently qualified for aseptic operations.

B. Despite positive environmental monitoring results in the ISO 5 area, your firm released batches of drug products intended to be sterile without investigation or scientific justification. For example, your firm reported microbial growth during environmental monitoring of the ISO 5 area and performed microbial identification, as follows:

- Semaglutide 10 mg/4 mL, Lot# PRORX050925-1, Mfg. Date: (b) (4) , BUD: November 5, 2025 - 1 CFU of Corynebacterium sp. detected on left fingertips.
- Semaglutide 10 mg/4 mL, Lot# PRORX051425-6, Mfg. Date: (b) (4) , BUD: November

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	Taichun Qin, Investigator X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 09-19-2025 09:48:23	9/19/2025

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10, 2025 - 1 CFU of Bacillus subtilis detected on left fingertips.

- Semaglutide 5 mg/2 mL, Lot# PRORX052125-4, Mfg. Date: (b) (4), BUD: November 17, 2025 - 1 CFU of Bacillus filamentosus detected on left fingertips.
- Tirzepatide 27 mg/3 mL, Lot# PRORX08062025-3, Mfg. Date: (b) (4), BUD: April 3, 2026 - 1 CFU of Bacillus subtilis detected on right fingertips.
- Semaglutide 12.5/5ml, Lot# Prorx04282025(b) (4) Mfg: (b) (4), BUD: October 25, 2025 - 2 CFUs of Bacillus subtilis detected on the settle plate.
- Semaglutide Injection, 5 mg/2 mL (2.5 mg/ml), Lot# Prorx041125(b) (4), Mfg: (b) (4), BUD: October 8, 2025 - 1 CFU detected on the settle plate

No documented investigations were conducted for these positive results. Your firm released the affected batches based on the rationale that the microorganisms were not highly pathogenic, without neither adequate consideration of sterility assurance nor whether organisms would be pathogenic if injected into the body, especially for patients that are or might be immune compromised. Additionally, your firm failed to conduct microbial identification testing for Semaglutide Injection, 5 mg/2 mL (2.5 mg/ml), Lot# Prorx041125(b) (4).

Your firm identified positive microbial growth within ISO 5 areas during (b) (4) environmental monitoring - 2 CFUs of Bacillus subtilis and Calcarisporium cordycipiticola recovered from surface sampling on April 11, 2025. The surface sampling was conducted after cleaning of the ISO 5 hoods, as confirmed by the responsible personnel. Your firm produced three batches on that day - Semaglutide 5mg_2mL, Lot# Prorx041125-3, NAD+ 1200mg_6mL, Lot# Prorx04112025(b) (4), and NAD+ 1200mg_6mL, Lot# Prorx04112025(b) (4). All affected batches were released and distributed to your customers without an investigation.

C Your firm failed to investigate microbial growth exceeding action levels in the ISO 7 and ISO 8 areas during environmental monitoring, personnel monitoring, and gown qualification. For example, Operator (b) (6), (b) (7) exhibited the following microbial recoveries during gowning on May 29, 2025: 7 CFU from the fingertips, 17 CFUs on the left gown, and 20 CFUs on the right gown. No investigation was conducted

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for this nonconformance. On January 16, 2025, air sampling of the ISO 7 area detected 1 CFU of Trichoderma orientale (mold) during the production of Tirzepatide 60 mg/3 mL. No investigation was initiated or for other similar occurrences.

D. The investigation of positive environmental monitoring results for mold detected on operators' fingertips while working in the ISO 5 area was inadequate, as described below.

- Semaglutide 6 mg/2.4 mL, Lot# PRORX051425-1, Mfg. Date: (b) (4), BUD: November 10, 2025 - 1 CFU of Aspergillus niger detected on left fingertips and 2 CFUs of Kocuria turfanensis and Aspergillus eucalypticola/tubinensis/vadensis detected on right fingertips.
- Semaglutide 2.5 mg/1 mL, Lot# PRORX051525-6, Mfg. Date: (b) (4), BUD: November 11, 2025 - 2 CFUs of Brevibacterium frigoritolerans and Aspergillus niger detected on right fingertips.

Despite mold detected on two consecutive days during personnel monitoring, your investigation indicated that the positive results posed no risk to patients or products, and only minimal risk to the process given the passing sterility test results of finished products. Additionally, your investigation failed to extend to other batches produced by the affected operators during the same period to date. Your firm produced batches on April 14 and April 15, 2025, which were released and described as follows:

- Semaglutide 6mg/2.4mL , Lot# Prorx051425-2, BUD: November 14, 2025
- Semaglutide 6mg/2.4mL, Lot# Prorx051425-3, BUD: November 14, 2025
- Semaglutide 6mg/2.4mL, Lot# Prorx051425-4, BUD: November 14, 2025
- Semaglutide 10mg/4mL, Lot# ProRx051425-5, BUD: November 14, 2025
- Semaglutide 10mg/4mL, Lot# ProRx051425-6, BUD: November 14, 2025
- Semaglutide 8mg/3.2mL, Lot# Prorx051525-1, BUD: November 15, 2025
- Semaglutide 8mg/3.2mL, Lot# Prorx051525-2, BUD: November 15, 2025
- Semaglutide 8mg/3.2mL, Lot# Prorx051525-3, BUD: November 15, 2025

- Semaglutide 8mg/3.2mL, Lot# Prorx051525-4, BUD: November 15, 2025
- Semaglutide 2.5mg/1mL, Lot# Prorx051525-5, BUD: November 15, 2025

E. Investigation of non-conformance results significantly exceeded the required timeframe without justification. Your firm established a due date of July 2, 2025, for investigating positive environmental monitoring results involving mold detected on operators' fingertips on June 11. 2025 during production of Semaglutide 6 mg/2.4 mL, Lot# PRORX051425-1, and Semaglutide 2.5 mg/1 mL, Lot# PRORX051525-6. The investigation has not been closed; however, no justification was documented and approved for the extended investigation timeline.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Environmental monitoring during aseptic production of sterile drug products is inadequate, as described below:

• Non-viable particle counting in ISO Class 5 LAFH or BSC is conducted only every (b) (4) during clean room certification by a third-party company, according to SOP 03-05.02, "Viable and Non-Viable Sampling," dated February 2025. The two most recent clean room certifications were issued on (b) (4) (b) (4), and (b) (4), during which non-viable particles were measured in the ISO Class 5 hoods; however, no non-viable particle monitoring is conducted during routine batch processing.

• Although settle plates are used during production of each batch, active air monitoring is conducted only (b) (4) per the SOP; however, the Viable Air Sampling Log shows that viable air sampling was

not performed in (b) (4), and (b) (4). No active air monitoring is conducted during routine batch processing.

• Surface monitoring is performed on a (b) (4) basis per the SOP; however, the surface Sampling Log shows that surface monitoring was not performed in (b) (4), and (b) (4). No surface sample monitoring is conducted during routine batch processing.

On September 9, 2025, it was observed that non-viable particles, active air, and surface samples were not monitored during aseptic processing of Tirzepatide Injection 45 mg/2.5 mL, Lot# Prorx09092025(b) (4); Tirzepatide Injection 45 mg/2.5 mL, Lot# Prorx09092025(b) (4); and Glutathione 2,000 mg/10 mL, Lot# Prorx092025(b) (4).

Your firm produced (b) (4) batches of sterile drug products from June 2, 2025, to September 9, 2025.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. Aseptic techniques were not adequately demonstrated during aseptic processing operations. On September 9, 2025, during the production of Tirzepatide Injection 45 mg/2.5 mL, Lot# Prorx09092025(b) (4); Tirzepatide Injection 45 mg/2.5 mL, Lot# Prorx09092025(b) (4); and Glutathione 2,000 mg/10 mL, Lot# Prorx092025(b) (4), the following deficiencies were observed:

• The operator working in the ISO Class 5 area disrupted unidirectional airflow by extending their forearms over the container to retrieve each stopper and place it onto a vial during the stoppering process inside the ISO Class 5 hood

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• An operator working in the ISO Class 5 area had exposed forehead skin.

• The operator with exposed forehead returned to the ISO Class 8 gowning area to readjust safety goggles and subsequently reentered the ISO Class 7 buffer room without changing garments.

• During the gowning process, personnel in the unclassified area opened the door twice to pass supplies to an operator who was donning sterile garments.

• Cart wheels were not disinfected when moving from unclassified areas to the ISO Class 8 gowning room or when moving from the ISO Class 8 gowning room to the ISO Class 7 buffer room.

• An operator cut open the outer packaging of stoppers in the ISO Class 7 area. The inner bag was then transferred from the ISO 7 area into the ISO Class 5 laminar airflow workstation (LAFW) without surface disinfection. The inner bag of stoppers could be held for up to (b) (4) within the ISO 7 area before being transferred into the operator working in the ISO Class 5 area.

• An operator working in the ISO Class 7 area transfered stopper bags into the ISO Class 5 LAFW and cut open the packaging using non-sterilized scissors that were routinely stored in the ISO Class 7 area although it was wiped with sterile (b) (4) wipe prior to use.

Your firm produced (b) (4) batches of drug products intended to be sterile from June 2, 2025, to September 8, 2025.

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

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Specifically,

A. Your media fill studies did not simulate the aseptic vial manufacturing process under worst-case conditions, as described below.

• Personnel media fill studies do not simulate the batch production process. Personnel media fill qualification is conducted (b) (4) for each operator with multiple operators involved in a single media fill, with each individual operator filling (b) (4) trays of vials (up to (b) (4) vials) and stoppering those filled vials. For example, (b) (4) operators conducted personnel media fill qualification on June 2, 2025, with each individual filling and stoppering (b) (4) trays from a batch of (b) (4) vials (10 mL/vial). However, during batch production, two operators work together within the ISO Class 5 Laminar Airflow Hood (LAFH) or Biological Safety Cabinet (BSC) - one operator responsible for filling all vials of a batch (up to (b) (4) trays of (b) (4) units) and the other for stoppering. Operators who pass the initial media fill are qualified to work in the ISO Class 5 area to produce drug products intended to be sterile.

• Process validation media fills do not fully represent the batch production process under worst-case conditions. Your firm completed (b) (4) media fill batches for process validation with (b) (4) operators working within the ISO Class 5 LAFH or BSC simultaneously during media fill; however, the number of units filled, duration, and batch size do not simulate the batch production process. For example, (b) (4) (b) (4) filled (b) (4) vials (30.4 mL/vial) per media fill unit Prorx06172025 (b) (4) dated June 17, 2025, while (b) (4) operators filled (b) (4) vials (6 mL/vial) per Prorx03242025 dated April 10, 2025. During routine aseptic processing, a (b) (4) could fill up to (b) (4) vials (6 mL/vial) for a batch.

B. Growth promotion testing has not been conducted for (b) (4) plates used for environmental monitoring, including settle plates, surface samples, and personnel monitoring.

C. (b) (4) sterilization qualification is inadequate because biological indicators are not used for

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qualification. According to the "Qualification Mapping Analyses and Open-Door Study and (b) (4) Sterility Study, Validated_PRX7008" dated February 10, 2025, temperature mapping results met acceptance criteria; however, no biological indicators were used for qualification of (b) (4). This equipment is used for sterilization of utensils such as tweezers and scissors used in the ISO Class 5 area. The tweezers are used to add stoppers to vials during the filling of drug products intended to be sterile.

OBSERVATION 5

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the quality of drug products.

Specifically,

A. Your firm is constructing a new facility within the same building to manufacture sterile and non-sterile products, separated from the current sterile facility by only a wall. Construction activities (e.g., cleanroom build-out, equipment installation, floor renovation, and wall demolition) are ongoing while sterile manufacturing continues. No change control or risk assessment has been initiated. These activities pose a risk of cross-contamination and loss of environmental control due to particulate and microbial intrusion, personnel and material movement, and disruption of facility integrity.

B. Your firm has not adequately qualified operators conducting visual inspections of drug products intended to be sterile. For example, Operator (b) (6), (b) (7) performed visual inspection of Tirzepatide 72 mg/4 mL on September 10, 2025; however, operator visual qualification was based solely on eye examination records from physicians rather than comprehensive visual inspection competency testing, including using qualification kits containing critical, major and minor defects.

C. Visual inspection failed to accurately classify vial defects that were approved by the quality unit. For

example, the batch record for Semaglutide 5 mg/2 mL, Lot# PRorx04112025(b) (4), documented (b) (4) fibers and (b) (4) white particles, which were classified as minor. However, in the batch record for Semaglutide 12.5 mg/5 mL, Lot# 042825(b) (4) white particles were classified as major. Despite this inconsistency, both batches were reviewed and approved by the quality unit.

D. Your firm conducted 100% visual inspection of finished vials for each batch; however, no inspection using statistical sampling methods (e.g., AQL inspection) is performed by the Quality Unit as part of batch release.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Your firm has not conducted disinfectant efficacy studies for disinfectants used in the cleaning and disinfection of ISO Class 5 LAFH or BSC and cleanroom environments. The production operators used (b) (4) for disinfecting supply surfaces and (b) (4) cleaning and disinfection of ISO Class 5 hoods, while (b) (4) is used for (b) (4) disinfection and (b) (4) is used for (b) (4) disinfection of cleanrooms and ISO Class 5 hoods; however, your firm has not performed disinfectant efficacy studies for these disinfectants, despite various microorganisms exceeding action levels, including mold detected in both ISO 5 and ISO 7 areas during aseptic processing.

B. The floor of the ISO Class 7 buffer room equipped with an ISO Class 5 LAFH and BSC showed significant visible sporadic discoloration, the cause of which remains unknown.

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OBSERVATION 7

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your drug product labels:

A. The established name of the drug; Examples of your drug product labels that do not contain this information, include but are not limited to:

- NAD+ Injection 1200 mg (200 mg/mL), 6 mL Multidose Vial

B. The statement "Not for resale." Examples of your drug product labels that do not contain this information, include but are not limited to:

- Tirzepatide Injection 45 m/2.5 mL (18 mg/mL), 2.5 mL Multidose Vial
- NAD+ Injection 1200 mg (200 mg/mL), 6 mL Multidose Vial
- Glutathione Injection 2000 mg (200 m/mL), 10 mL Multidose Vial

***DATES OF INSPECTION**

9/09/2025(Tue), 9/10/2025(Wed), 9/11/2025(Thu), 9/12/2025(Fri), 9/15/2025(Mon), 9/16/2025(Tue), 9/17/2025(Wed), 9/18/2025(Thu), 9/19/2025(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."