DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center, Building 20 Sixth Avenue and Kipling Street Denver, CO 80225 Industry Information: www.fda.gov/oc/industry	3/25/2025-4/3/2025 FEI NUMBER 3033176989

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Doug Hatch, Owner

FIRM NAME	STREET ADDRESS
Thrive Health and Wellness, LLC, dba Thrive Health Solutions	88 Inverness Cir E Unit A204
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Englewood, CO 80112-5521	Sterile and 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) (WE) OBSERVED:

Observation 1

Lack of a certified ISO-5 classified area for sterile compounding

Specifically,

Your firm fills syringes intended for subcutaneous injection by withdrawing sterile solution from vials on a benchtop table, located in an unclassified room for the following products:

- Semaglutide for injection
- Tirzepatide for injection
- Cyanocobalamin for injection
- Lipoboost (B-complex) for injection
- Sermorelin for injection

The dosage of each product varies among patients or across different treatment levels. Your firm produced an average of approximately (b)(4) syringes a week. For example, on 3/24/2025, your firm produced approximately (b)(4) syringes of GLP-1 Semaglutide injections: Level 4 (1.7 mg/5mg/mL), Lot# 03075J, Discard by: 7/7/2025 and GLP-2 Tirzepatide: Level 4 (10 mg /30mg/ml), Lot# 03125A, Discard by: 9/12/2025. These syringes have been dispensed to patients.

Additionally, your firm assigned the beyond-use dates (BUDs) or discard-by date to all repackaged syringe products, which are the same as those of the original vials used for filling despite the lack of a certified ISO-5 classified area for repackaging syringes intended to be sterile. For example, the finished syringes of Tirzepatide for injection were assigned BUDs identical to those of the multi-dose vial used for filling. Two lots of syringes containing Tirzepatide injection produced on 3/24/2025 (Lot #03075J and Lot #03125A), were assigned BUDs of

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Taichun Qin	Taichun Qin, Investigator	4/3/2025

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7/7/2025, and 9/12/2025, respectively, which are identical to those of the two vials used for filling those syringes.

Observation 2
Failures to conduct media fills that simulate aseptic production operations.

Specifically,

The operators involved in repackaging vials into syringe products intended to be sterile have never conducted media fills. For example, on 3/25/2025, it was observed that the operator produced Tirzepatide/ Cyanocobalamin, 15mg/1mg/mL (5mL), Lot# 03065F, BUD: 7/6/2025; however, the operator has never conducted media fills. Your firm produced approximately (b) (4) syringes a week.

Observation 3
Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

Specifically,

Your firm filled the syringes containing products intended to be sterile on a benchtop table in an unclassified room that contains potential contaminants, as described below.

A. The benchtop table with shelves is cluttered with syringes, containers, utensils, binder clips, wipes, marker pens, and other supplies.

B. The room also serves as an office, equipped with a computer, chair, and telephone, and is congested with cardboard boxes, a storage cabinet, wall-mounted artwork, a refrigerator, and various other items.

C. The floor is covered with carpet, which makes cleaning difficult.

Observation 4
Personnel engaged in aseptic processing were observed wearing non-sterile gloves.

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Specifically,

Your firm uses non-sterile gloves in the production area. For example, on 3/25/2025, the operator was observed using non-sterile gloves during the filling of syringes of Tirzepatide/ Cyanocobalamin, 15mg/1mg/mL, Lot# 03065F, BUD: 7/6/2025, from a vial.

Observation 5
Use of a disinfectant in a manner insufficient to achieve adequate levels of disinfection.

Specifically,

A. Sporicidal agents are not used in the production area. Your firm uses non-sterile wipes and a multi-enzymatic cleanser to clean the production area and utensils. Sporidical agents have never been used, and none are available at your facility.

B. Your firm uses non-sterile disinfecting wipes to clean the production area. No sterile wipes intended for cleaning work surfaces were available at your firm.

C. The work surface is not disinfected prior to packaging vials into syringes. For example, on 3/25/2025, during the filling of syringes of Tirzepatide/ Cyanocobalamin, 15mg/1mg/mL, Lot# 03065F, BUD: 7/6/2025, from a vial, the operator failed to disinfect the work surfaces with appropriate wipes prior to use.

Observation 6
Personnel engaged in aseptic processing were observed with exposed hair and skin.

Specifically,

No gowns, head covers, or masks were used during the filling of syringes intended to be sterile. For example, on 3/25/2025, the operator, with exposed hair, did not wear any gown during the filling of syringes with Tirzepatide/ Cyanocobalamin, 15mg/1mg/mL (5mL), Lot# 03065F, from a vial.

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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."