DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	09/15/2026-09/28/2026* FEI NUMBER 3021042485

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jamin N. Schwehr, Pharmacist-in-Charge (PIC)

FIRM NAME	STREET ADDRESS
Strive Pharmacy LLC	1275 E Baseline Rd Ste 104
CITY, STATE, ZIP CODE, COUNTRY Gilbert, AZ 85233-1224	TYPE ESTABLISHMENT INSPECTED producer of sterile and nonsterile 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,

Periodic Air and Surface Environmental Monitoring

A. There was an action level (b) (4) active air sample in ISO 5 LFH[(b)] (Hood [(b)(4)] on 11/26/25. Sample ID #BHT112625NHDH1, result = 15 cfu, action limit for ISO 5 air samples is [(b)(4)] cfu. Microorganisms were identified as *Micrococcus* species and coag-negative *Staphylococcus* species. There was no additional investigation or corrective actions. Technicians do not document what specific activity was occurring in the LHF during sample collection. Technicians made about [(b) (4)] sterile drug lots inside LFH[(b)] on 11/26/25. Examples of batches produced and dispensed include Semaglutide 2.5 mg/mL, 2 mL solution for injection, batches LG364186933 and LG364186939.

Post-Batch [(b) (4)] and Surface Sampling

B. About [(b)(4)] post-batch [(b) (4)] and surface samples collected inside ISO 5 LFH or ISO 5 BSC during the previous year had at least 1 cfu after incubation. Additional disinfection and investigation were not always completed for below action level results, including recovery of mold and spore forming microorganisms. Most batches associated with these below the action level results were released. Examples of batches associated with below action level ISO 5 growth include:

- Semaglutide/Glycine/B12 injection, 5/5/1 mg/mL, 0.5 mL, batch LG364285563, expiration 10/25/26, post-batch [(b) (4)] sample ID #DJO072726, result = 1 CFU *Alternaria* species. The batch Production Record Checklist inaccurately lists the [(b) (4)] result as <1 CFU, and personnel did not complete the required evaluation for [(b) (4)] growth. The entire lot was dispensed to fill more than [(b) (4)] prescriptions.
- Semaglutide/Glycine/B12 5/5/1 mg/mL, 2 mL, batch LG364281132, sample ID #GD071926LH, result = 3 cfu *Bacillus* species, coagulase-negative *Staphylococcus* species, and *Micrococcus* species. This lot was dispensed.
- Tirzepatide/Glycine/B12 10mg/5mg/500mcg/mL injection, 4 mL, batch LG364238721, sample ID #OYM032526LH, result = 1 cfu *Bacillus* species. This lot was dispensed.

OBSERVATION 2

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EMPLOYEE(S) SIGNATURE
Nicholas L Hunt, Senior CSO

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Senior CSO
Signed By: Nicholas L. Hunt -S
Date Signed: 09-28-2026
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Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically, sterile production technicians did not always use slow and deliberate movements in the ISO 5 LHFs and ISO 7 Buffer Rooms. Technicians moved quickly during cleaning, LHF setup, and filling and stoppering of multiple sterile injectable drugs on 09/15/26.

OBSERVATION 3
Use of non-sterile disinfecting agents and cleaning wipes in the ISO 5 area and classified areas.

Specifically, sterile (b) (4) wipes, bottles of sterile (b) (4) solution, and bottles of sterile (b) (4) remained open in the ISO 7 Buffer Rooms indefinitely while technicians actively used these items to disinfect and clean items that entered the ISO 5 LHF and ISO 7 Buffer Rooms on 09/15/26.

OBSERVATION 4
Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically,

A. Nonsterile production technicians in the hazardous room do not always follow the deactivate, decontaminate, and clean process. Technicians did not adequately deactivate or decontaminate mixing blades, spatulas, glass beakers, and various (b) (4) removable parts that directly contact hazardous drugs. I watched multiple technicians wipe equipment and utensils with a single-use wipe (b) (4) with (b) (4) or (b) (4), immediately rinse the items with tap water, wash the items with tap water and (b) (4), and then place them on a drying rack.

B. Red spatula with unknown white residue and powder, black spatula with unknown white residue and powder, (b) (4) with unknown white residue and a brownish particulate, scraper with unknown white residue and powder. All these items were observed to be comingled with other utensils and were designated clean and ready for use.

C. The mouse, keyboard, (b) (4) scanner, and (b) (4) at the workstation for each of the (b) (4) (b) (4) (b) (4) in the hazardous production room were not deactivated, decontaminated, and cleaned adequately. I watched a technician use the mouse at the workstation next to Hood (b) on multiple days. The mouse contained visible white residue in the seams every time I examined it. I watched multiple technicians remove their hands from the (b) (4) during active production and then use items at the workstation without decontaminating or changing gloves.

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D. (b) (4) Hood (b) (4) had a hole and an about two-inch-long open crack on the back wall of the unit. There was also a buildup of residue on the left side panel above the hinge for the front panel.

E. The work surfaces in (b) (4) Hood (b) (4) Hood (b) (4) Hood (b) (4) and Hood (b) (4) contained excessive scratches, pits, and other wear that made the surfaces not smooth and easily deactivated, decontaminated, and cleaned.

OBSERVATION 5

Smoke studies were inadequately performed under dynamic conditions.

Specifically, smoke studies did not introduce smoke into the entire ISO 5 LFH to confirm unidirectional airflow throughout the aseptic processing area. Additional technicians in the ISO 7 Buffer Rooms during the smoke studies were stationary which was not representative of routine production. I reviewed the most recent smoke studies completed in April 2026 for Hood (b) (and Hood (b) in Lane (b) (4 and completed in May 2026 for Hood (b) (and Hood (b) (in Lane (b) (4 Technicians produced all sterile injectable drugs in these LFH which includes more than (b) (4) sterile drug vials in the previous three months.

OBSERVATION 6

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

Specifically,

A. There was visible adhesive facing upward on the partially unsecured tape attempting to secure the damaged height adjustment control panel underneath the worksurface of ISO 5 Hood (b) (The exposed adhesive was within six inches of the seated technician filling multiple lots of Semaglutide 2.5 mg/mL on 09/15/26.

B. There is a large glassware washing sink and a small hand washing sink in the ISO 8 Anteroom. Technicians wash and dry all glassware used during sterile compounding/formulation in the ISO 8 Anteroom before it is transferred to another room for (b) (4) preparation. Sterile production technicians gown within a few feet of these sinks. The ISO 8 Anteroom is connected to both ISO 7 Prep Rooms used to formulate drugs. Both ISO 7 Pre Rooms are connected to ISO 7 Buffer Rooms that contain ISO 5 LFHs used to sterile (b) (4) and fill finished drugs.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Nicholas L Hunt, Senior CSO	X Nicholas L Hunt Senior CSO Signed By: Nicholas L. Hunt -S Date Signed: 09-28-2026 14:07:40	09/28/2026

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C. There was apaprent corrosion and damage to the bottom of multiple (b) (4) door frames where they met the floor in the cleanroom.

OBSERVATION 7
Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, I watched a sterile production technician don sterile garb inside the ISO 8 Anteroom about two to four feet away from a laboratory support technician who was manually washing about 15 soiled glassware items in the approximately four-foot-wide sink. The production technician entered the Lane (b) (4) ISO 7 Prep Room. Flow of materials and personnel: ISO 8 anteroom → ISO 7 Prep Rooms → ISO 7 Buffer Rooms.

OBSERVATION 8
Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, media fills are not always conducted under the most challenging and stressful conditions. Technicians work (b) (4) shifts, but there is no requirement for media fills to occur at the end of a technician's shift when they are presumably most fatigued. The end of the shift ensures the technician would have interacted with the most materials, personnel, environment, and other items that could contribute to particulates, microorganisms, or other contaminants in the media fill.

OBSERVATION 9
Inadequate routine environmental monitoring in the classified areas.

Specifically, stools positioned at all (b) (4) ISO 5 LFH are not included in the EM surface sample program. I observed technicians in the Lane (b) (4) ISO 7 buffer room and the Lane (b) ISO 7 buffer room directly contact a stool with their gloved hands during filling operations for sterile injectable drugs. Technicians sit on the stools while filling. Technicians sit on a bench in the ISO 8 anteroom while donning sterile gowning. The anteroom bench is approximately than one-foot-away from the hand washing sink and four-foot-away from the glassware washing sink.

OBSERVATION 10
Lack of adequate personnel sampling.

Specifically, a pharmacist who was performing (b) (4) assessment on 09/16/26 cracked both (b) (4) plates all the way across and through the depth of the (b) (4) Also, an approximately 1-inch piece broke off the side of the (b) (4) plate lid and fell onto the (b) (4) surface. The QA Technician administering the assessment did not invalidate the assessment and incubated the damaged plates. Damaged (b) (4) surface can inhibit growth of microorganisms.

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***DATES OF INSPECTION**
9/15/2026(Tue), 9/16/2026(Wed), 9/17/2026(Thu), 9/18/2026(Fri), 9/21/2026(Mon), 9/22/2026(Tue), 9/23/2026(Wed), 9/24/2026(Thu), 9/25/2026(Fri), 9/28/2026(Mon)

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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."