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	8/14/2023-9/8/2023*
	FEI NUMBER 3015826784

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christopher C. Freeman, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Strive Pharmacy Texas LLC dba Strive Pharmacy	1430 S Main St Ste 105
CITY, STATE, ZIP CODE, COUNTRY Boerne, TX 78006-3334	TYPE ESTABLISHMENT INSPECTED Producer (Compounder) of Sterile & Non-sterile Drug Products

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

The facility design was observed to allow the influx of lesser quality air into a classified area containing higher quality air.

Specifically,

A. During an inspection of your ISO 7 classified cleanroom, a gap approximately 2-inches wide was observed between the edge of the flap and the (b) (4) cleanroom corner, along the back wall of the cleanroom. The opening exposes the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced, to the lower quality air of the surrounding unclassified space (i.e., the "general pharmacy area"). It is further observed that this unclassified space houses difficult to clean items, particle generating equipment (e.g., (b) (4) and is where non-sterile hazardous drug products are produced.

B. Your unclassified (b) (4) , used to transfer materials between the ISO 7 classified cleanroom and the unclassified general pharmacy area may allow the influx of lower quality air into the cleanroom, which houses an ISO 5 classified hood where drug products intended to be sterile are produced. The (b) (4) is not supplied with HEPA-filtered air. It is further observed that this unclassified space houses difficult to clean items and particle generating equipment (e.g., (b) (4)

OBSERVATION 2

Personnel performed aseptic manipulations with exposed hair or skin.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator	X Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 09-08-2023 11:57:5	9/8/2023

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Specifically, on 8/14/2023, during aseptic processing observations, I observed your firm's compounding pharmacy technician exhibit poor aseptic practices by allowing her head to cross into ISO5 LAF unit exposing facial skin and hair while processing the drug product, Semaglutide/B12 2/1 mg/ml (1ml) Inj., Lot ID LG10989644, Date Made 8/14.2023/ Expiry 9/28/2023 drug product intended to be sterile.

OBSERVATION 3

Failure to appropriately and regularly clean and disinfect or sterilize equipment located in the ISO 5 area.

Specifically, vial crimpers are stored in the unclassified area. When transferred to the ISO 7 classified cleanroom, and then to the ISO 5 classified hood, they are subject only to sanitization by spraying with (b) (4) and wiping with a sterile wipe. Considering their design (i.e., moving parts and small, difficult to access crevices, etc.), there is no assurance your method of cleaning is effective in: (1) disinfecting the crimpers, and (2) removing debris and other reside. Consequently, use of the crimpers in this manner, without adequate cleaning and disinfection poses a contamination risk to your drug products.

OBSERVATION 4

Cleaning of equipment and glassware is inadequate.

Specifically, prior to sterilization, glassware, and utensils, used to produce drug products intended to be sterile, are cleaned and sanitized with household detergents, including (b) (4) dish detergent (for hand washing) and (b) (4) (for dishwashing machine). There is no assurance that your cleaning process is adequate to remove detergent residue from glassware and other utensils.

***DATES OF INSPECTION**

8/14/2023(Mon), 8/15/2023(Tue), 8/16/2023(Wed), 8/17/2023(Thu), 8/18/2023(Fri), 8/21/2023(Mon), 8/22/2023(Tue), 8/23/2023(Wed), 8/24/2023(Thu), 8/25/2023(Fri), 8/28/2023(Mon), 9/08/2023(Fri)

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Camerson E Moore, Investigator

X Camerson E Moore
Investigator
Signed By: Camerson E. Moore - S
Date Signed: 09-08-2023 11:57:5

DATE ISSUED
9/8/2023

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."