DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	2/13/2023-3/2/2023* FEI NUMBER 3021886842

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Fayez Faraj, Owner and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Snf Holdings, LLC	31035 Schoolcraft Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Livonia, MI 48150-2029	Producer of 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 WE OBSERVED:

OBSERVATION 1

You produced hazardous drugs without providing adequate segregation, cleaning of work surfaces and cleaning of utensils to prevent cross-contamination.

Specifically,

A. All hazardous and non-hazardous drug products produced onsite use shared production and cleaning equipment; this includes, but is not limited to, the following: biological safety cabinets (BSCs), capsule machines, analytical balances, electric mortar and pestles, mixing jars, mixing blades, scrub brushes, and utensils. Current cleaning methods do not include the use of deactivating agents after production of hazardous non-sterile drug products.

B. We observed operators routinely touching ancillary equipment, such as calculators, keyboards, computer mice, and printers, that contained apparent white powder while producing drug products. These pieces of ancillary equipment are not routinely cleaned and are not product dedicated. For example, the above activities were observed on 02/13/2023 during production of Ivermectin 20 mg capsules lot #02102023@(b) (4) the operator did not change or sanitize gloves between touching different pieces of equipment and proceeded to handle finished capsules. The operators' hands were in contact with a keyboard outside of the BSC as well as with a mouse, calculator, and scanner inside the BSC.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jacob G Lutz, Investigator Alan M Barker, Investigator Wen Ning Chan, Investigator	X Jacob G Lutz Investigator Signed By 2002879082 Date Signed 03-02-2023 11:01:45	3/2/2023

C. During production operations, operators dispose of waste in hazardous waste bags located on the inside of BSCs; we observed operators placing their gloved hands inside of these bags to dispose of waste. These bags are not changed between different product formulations. For example, the above activities were observed on 02/14/2023 during production of DHEA/Progesterone SR 20/100 MG Capsules lot #02132023@(b)(4), which was followed by production of Ivermectin 22.5 MG Capsules lot #02142023@(b)(4) which was followed by production of Progesterone SR 25 MG Capsules lot #02132023@(b)(4), all in the same hood.

D. Operators do not change gloves between different product formulations. For example, we observed production of DHEA/Progesterone SR 20/100 MG Capsules lot #02132023@(b)(4), which was followed by production of Ivermectin 22.5 MG Capsules lot #02142023@(b)(4) which was followed by production of Progesterone SR 25 MG Capsules lot #02132023@(b)(4) all in the same hood; the operator did not change gloves between production of formulations above.

OBSERVATION 2

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Since 01/01/2021, approximately(b)(4) lots of drug product have been reportedly produced using (b) (4) (b) (4)" (b) (4) ; in the same time period, approximately(b)(4) lots of drug product produced include a component called "(b) (4) ", which is reportedly produced using (b) (4) (b) (4) (b) (4) . These (b) (4) have not been shown to be suitable for use in the production of non-sterile drug products. For example: (b) (4) was used to produce N45-GENTA/IBU/ITRA/MUPI/TERB/UREA 0.2/2/1/3/1/20% solution on 02/10/2023; (b) (4) lot #(b) (4) was produced on 01/19/2023 and was used to produce ketamine nasal spray 100 mg/mL

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spray lot #02092023@(b)(4)

OBSERVATION 3

Non-microbial contamination was observed in your production area.

Specifically,

A blue residue was observed along the back edge of the biological safety cabinets (BSCs) used in the production of all capsules made onsite. The blue residue was observed where the stainless-steel top and back white wall of the BSC adjoin. This residue was observed to be present during the capsuling of T4/T3 (Biothyroid) SR 300/6 MCG Capsule lot #02142023@(b)(4) A blue residue was also observed sandwiched between the sides of the stainless-steel top and the glass side wall panel of BSCs used in production of all capsules. This blue residue was observed on multiple days throughout the inspection inside of the BSCs.

***DATES OF INSPECTION**

2/13/2023(Mon), 2/14/2023(Tue), 2/15/2023(Wed), 2/16/2023(Thu), 2/17/2023(Fri), 2/22/2023(Wed), 3/01/2023(Wed), 3/02/2023(Thu)

X Alan M Barker
Investigator
Signed By: 2001639387
Date Signed: 03-02-2023 11:03:05

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jacob G Lutz, Investigator Alan M Barker, Investigator Wen Ning Chan, Investigator	X Jacob G Lutz Investigator Signed By: 2002879082 Date Signed: 03-02-2023 11:01:45	3/2/2023

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."