DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100	09/26/2022 – 09/28/2022
	FEI NUMBER 3012814943
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jamie L. Bergland, Pharm D, RPH, Pharmacist-in-Charge	
FIRM NAME MSLS LLC dba The Medicine Shoppe	STREET ADDRESS 1405 NE Douglas
CITY, STATE, ZIP CODE, COUNTRY Lees Summit, MO 64086	TYPE ESTABLISHMENT INSPECTED 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

Non-microbial contamination was observed in your production area.

Specifically,

On 09/26/2022, the technician was observed producing approximately (b) (4) hormonal and non-hormonal non-sterile human drug products (i.e. Progesterone 75mg capsules, Rx number (b) (6) , expires 03/25/2023) and one non-sterile animal drug product (Methimazole 1.25mg/0.1mL in Lipoderm cream 6mL, Rx number (b) (6) expires 12/25/2022, intended species feline) in the drug compounding lab during which the following were observed:

- Apparent residue build-up around and behind the sink where all glassware and utensils used in production of non-sterile human and animal drug products are cleaned. Additionally, on 09/26/2022 your technician was observed using the glass slab that was stored behind the sink to produce non-sterile human drug products (i.e. Ketoprofen/Lidocaine 20/5% cream, batch number 092622KETO, expires 03/25/2023). Your technician did not clean the glass slab prior to use.
- Apparent thick, black residue build-up on the return vent located in the ceiling.
- Apparent residue build-up behind the (b) (4) magnetic stir plates used to mix hormonal and non-hormonal non-sterile human and animal drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lauren N. Howard Jill J. Tillman	Lauren N. Howard, Investigator Jill J. Tillman, Investigator	09/28/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100	09/26/2022 – 09/28/2022 FEI NUMBER 3012814943
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jamie L. Bergland, Pharm D, RPH, Pharmacist-in-Charge	
FIRM NAME	STREET ADDRESS
MSLS LLC dba The Medicine Shoppe	1405 NE Douglas
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lees Summit, MO 64086	Producer of Non-Sterile Drug Products

OBSERVATION 2

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

Specifically,

a. On 09/26/2022 in the drug compounding lab, your technician was observed running through the (b) (4) mill (b) (4) commercially available non-pharmaceutical grade cleaning agents that may leave residues and using approximately (b) (4) of water to rinse the cleaning agents off the mill. The following non-sterile human drug products are processed through the non-dedicated mill:
   - all topical lidocaine powder containing mixtures
   - all topical gabapentin powder containing mixtures
   - salicylic acid containing cream ((b) (4) batched cream)
   - all topical ibuprofen powder containing mixtures

b. According to your technician, clear plastic bowls used to cover pre-weighed hormonal and non-hormonal human and animal drug powders are never cleaned unless visible residue is detected on them. On 09/26/2022, we observed bowls being used to cover pre-weighed hormonal powders for trouches which had visible residue on them. Your technician stated if the bowls are cleaned, a non-pharmaceutical grade detergent is used. The following trouches were compounded for human use:
   - Estriol/Estradiol ((b) (4) 2mg/Progesterone 175mg/Testosterone 1.25mg/DHEA 1.25mg, Rx number (b) (6), expires 03/25/2023, picked up by patient

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lauren N. Howard Jill J. Tillman	Lauren N. Howard, Investigator Jill J. Tillman, Investigator	09/28/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100	09/26/2022 – 09/28/2022 FEI NUMBER 3012814943
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jamie L. Bergland, Pharm D, RPH, Pharmacist-in-Charge	
FIRM NAME MSLS LLC dba The Medicine Shoppe	STREET ADDRESS 1405 NE Douglas
CITY, STATE, ZIP CODE, COUNTRY Lees Summit, MO 64086	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

- Estriol/Estradiol ((b) (4)) 1.85mg/Progesterone 185mg/Testosterone 0.25mg/DHEA 1mg/Pregnenolone 25mg, Rx number (b) (6) , expires 02/02/2023, picked up by patient
- Estradiol 1mg/Progesterone 200mg/Testosterone 3mg, Rx number (b) (6) expires 03/25/2023, picked up by patient
- Estriol/Estradiol (b) (4)) 3.75mg/Progesterone 130mg/Testosterone 1.5mg/DHEA 10mg/Pregnenolone 50mg, Rx number (b) (6) expires 03/25/2023, picked up by patient
- Progesterone 200mg/Testosterone 0.5mg, Rx (b) (6) , expires 03/25/2023, picked up by patient
- Estriol/Estradiol (b) (4) 0.75mg/Progesterone 100mg/Testosterone 0.3mg/DHEA 1mg, Rx number (b) (6) , expires 02/02/2023, picked up by patient

c. To clean all non-dedicated utensils and glassware used to produce non-sterile hormonal and non-hormonal human and animal drug products, your pharmacy is using a commercially available non-pharmaceutical grade detergent that may leave residues or not be adequately rinsed from the utensils and glassware. Additionally, a deactivating agent is not used for non-dedicated utensils and glassware used to produce both hormonal and non-hormonal drug products to prevent cross-contamination. On 09/26/2022, in the drug compounding lab, while your technician was producing Estriol/Estradiol ((b) (4) 3.75mg/Progesterone 130mg/Testosterone 1.5mg/DHEA 10mg/Pregnenolone 50mg trouches, Rx number (b) (4), (b) (6) expires 03/25/2023, the glassware being used to mix and dissolve the drug powders had an apparent residue on it.

OBSERVATION 3

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lauren N. Howard Jill J. Tillman	Lauren N. Howard, Investigator Jill J. Tillman, Investigator	09/28/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 913-495-5100	09/26/2022 – 09/28/2022
	FEI NUMBER 3012814943
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Jamie L. Bergland, Pharm D, RPH, Pharmacist-in-Charge	
FIRM NAME MSLS LLC dba The Medicine Shoppe	STREET ADDRESS 1405 NE Douglas
CITY, STATE, ZIP CODE, COUNTRY Lees Summit, MO 64086	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

Specifically,

On 09/26/2022, your pharmacy produced Triamcinolone 0.1% Rinse for human use, Rx number (b) (6), expires 10/26/2022, using (b) (4) batch number (b) (4). The label for the (b) (4) does not state it is pharmaceutical grade (b) (4) Additionally, the label in part states the source of the (b) (4) is " (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Lauren N Howard Jill J Tillman	Lauren N. Howard, Investigator Jill J. Tillman, Investigator	09/28/2022

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."