DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	3/20/2023-4/4/2023*
	FEI NUMBER 3004603767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Shawn W. Needham, Pharmacist/Owner

FIRM NAME	STREET ADDRESS
JD & SN Inc.	1555 Pilgrim St
CITY, STATE, ZIP CODE, COUNTRY Moses Lake, WA 98837-4623	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 I OBSERVED:

OBSERVATION 1

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

Specifically,

Your firm cleans product contact equipment, glassware, and utensils with household cleaners after they are used for production of hazardous and potent drugs. There is no assurance that household cleaning detergent is effective in cleaning and removal of product and cleaning agent residue from shared production equipment, glassware, and utensils used in the production of hazardous and potent drugs to prevent cross-contamination.

A) There are no assurances product contact equipment, glassware, and utensils used during compounding of Hazardous Drugs such as testosterone and estrogen, are cleaned with a deactivation product sufficient to prevent cross contamination with other hazardous or non-hazardous compounds. Additionally, your firm has not demonstrated that utensils used in the compounding of hazardous compounds are delineated or discernable from any other equipment, glassware, and utensils used for the compounding of non-hazardous compounded drug products.

B) The walls and ceiling of the (b) (4) hoods are not identified to be cleaned between production of different Hazardous Drug products such as testosterone and progesterone. There are no assurances these surfaces are cleaned and maintained in a manner to prevent cross

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bryan L Mcguckin, Investigator	X Bryan L Mcguckin Investigator Signed By: Bryan L. Mcguckin -S Date S gned: 0 -0 -2023 06:26:03	4/4/2023

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contamination.

C) Your firm has not demonstrated appropriate air changes per minute are established and ensured negative pressure is maintained during compounding of Hazardous Drugs. The prevention of cross contamination cannot be assured as your facility is not designed to prevent the compounding of non-hazardous compounds adjacent to rooms in which these hazardous compounds, such as hormones, are compounded.

***DATES OF INSPECTION**

3/20/2023(Mon), 3/21/2023(Tue), 3/22/2023(Wed), 4/03/2023(Mon), 4/04/2023(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bryan L Mcguckin, Investigator	X Bryan L Mcguckin Investigator Signed By: Bryan L. Mcguckin -S Date S gned: 0 -0 -2023 06:26:03	4/4/2023

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."