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	6/28/2017-7/12/2017*
	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Cleaning of production and processing areas, equipment and utensils used for the production of highly potent and hazardous drugs are inadequate to prevent cross contamination. For example:

A) (b) (4) hoods have residual (b) (4) drug product on the work surfaces, walls and ceiling after end of production cleaning on 6/29/17. For example, the (b) (4) hood in the (b) (4) room have (b) (4) residual on the touch screen of the (b) (4) balance, (b) (4) (b) (4) on the turn knob on the encapsulation machine, (b) (4) on the exterior of the encapsulation machine, and built-up in the grooves in the work table. Your current practice does not require the cleaning of the work surfaces prior to the start of production the following morning.

B) There is no assurance that household cleaning detergent is effective in cleaning and removal of drug residuals on shared production equipment and utensils used in the production of hazardous and potent drugs. Your current cleaning practice is to soak and hand wash shared production equipment and utensils in the sink with commercial household dish detergent, followed by cleaning in the dishwasher with a commercial dishwasher detergent. According to your cleaning procedure, equipment and utensils that are not dishwasher safe such as (b) (4) are hand washed with a commercial household dish detergent and air dried. No sanitizing agent is used for production equipment and utensils. You produce hazardous drugs estradiol, progesterone, methimazole, fluconazole, methyltestosterone, testosterone, and tretinoin.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tracy Li, Investigator	X Tracy K. Li -S	7/12/2017

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C) The walls and ceiling of the (b) (4) hoods are not cleaned between production of drugs to remove (b) (4) drug residuals leftover from processing. Your current practice is to only clean the work table in the (b) (4) hoods with a (b) (4) based cleaning wipe between each drug.

D) Yellow stains were observed on the ceilings of (b) (4) model (b) (4) Oven used in the processing of (b) (4) . There is no cleaning of the oven and the oven racks appeared to be dirty with built-up.

***DATES OF INSPECTION**

6/28/2017(Wed),6/29/2017(Thu),6/30/2017(Fri),7/06/2017(Thu),7/07/2017(Fri),7/12/2017(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tracy Li, Investigator	X Tracy K. Li -S	7/12/2017

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

Date: September 14, 2017

Shawn W. Needham
JD & SN Inc.
1555 Pilgrim St
Moses Lake, WA 98837-4623

Subject: System Notification

Dear Shawn W. Needham,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to AskORAIT@fda.hhs.gov.

Sincerely,

Lisa Creason
Director, Office of Information Systems Management
Office of Regulatory Affairs
Food and Drug Administration