### 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) 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.
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)
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