DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Cincinnati District Office 6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772 Industry Information: www.fda.gov/oc/industry	7/16/2018-7/26/2018*
	FEI NUMBER 3007957196

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gregory M. Killmeier, Pharmacist

FIRM NAME	STREET ADDRESS
Nutrishare Inc	11020 Plantside Dr
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Louisville, KY 40299-6105	Producer of Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, on 07/16/2018, employees were observed blocking first pass air with their gloved hands when removing air out of filled TPN bags. Employees were observed blocking first pass air when setting up new TPN bags, (b) (4) and ingredients on the (b) (4) of the (b) (4) to produce sterile drug products. During the production of prescription reference number (b) (6), an employee was observed placing their hand in front of the first pass air when making connection to the new bag. The employee was also observed blocking the first pass air while removing out the remaining air in the filled TPN bag for prescription reference number (b) (6).

OBSERVATION 2

ISO 5 classified areas were not certified under dynamic conditions.

Specifically, the smoke studies performed to demonstrate the laminar air flow in the (b) (4) laminar air flow hood used to produce sterile drug products do not have enough smoke to visualize the air flow. Critical operations such as setting up (b) (4) for the (b) (4), engaging and disengaging the TPN bag while on

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the (b) (4) , and removing out air from the TPN bags were not performed during the smoke study within the ISO 5 hoods.

OBSERVATION 3
The facility design is designed and operated in a way that permits poor flow of materials.

Specifically, employees in the ISO 7 cleanroom have access and utilize refrigerators that is shared with the warehouse, an unclassified area. On multiple occasions, employees were observed placing finished sterile TPN bags and other drug products in grey bins into two of the (b) (4) refrigerators that are (b) (4) of the ISO 7 cleanroom. However, staff in the warehouse can access the same refrigerators to retrieve the sterile drug products to remove and store them in the remaining (b) (4) refrigerators. There is no assurance that the unclassified area air is not entering the ISO 7 cleanroom upon opening the refrigerator (b) (4) finished sterile drug products.

OBSERVATION 4
Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, employees were observed taking vials of ingredients from the storage area under the ISO 5 hood and putting them directly into the ISO 5 laminar flow hood without any decontamination step on multiple occasions.

OBSERVATION 5
Disinfecting agents used in the ISO 5 aseptic processing areas are not sterile.

Specifically, the (b) (4) and (b) (4) disinfecting agent used in the ISO 5 laminar flow hood is not labeled as sterile.

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OBSERVATION 6

The use of sporicidal agents in the cleanrooms and ISO 5 aseptic areas is inadequate.

Specifically, the (b) (4) contact time for the sporicidal agent, (b) (4), is not sufficient to achieve adequate levels of disinfection.

OBSERVATION 7

You produced beta-lactam drugs without providing adequate segregation, cleaning of work surfaces and cleaning of personnel to prevent cross-contamination.

Specifically, multiple sterile penicillin and cephalosporin drugs are produced in the same positive pressure ISO 5 laminar airflow hood as all other sterile drug products with only a (b) (4) decontamination step in between beta-lactam and non-beta-lactam drug production. There is no assurance that the cleaning of work surfaces prevent cross-contamination between sterile drug production. On 01/29/2018, prescription reference number (b) (6), piperacillin-tazobactam (ZOSYN) was prepared in the ISO 5 Laminar Air Flow hood 4 where only a (b) (4) decontamination step is required before producing other sterile drug products. On 01/29/2018, ethanol, multivitamin, and octreotide syringes were also made in the ISO 5 Laminar Air Flow hood 4. On 07/10/2018, prescription reference number (b) (6), ceftriaxone 1000mcg/50ml was prepared with (b) (4) in an (b) (4) in the ISO 5 Laminar Air Flow hood 4 where only a (b) (4) decontamination step is required before producing other sterile drug products. On 07/10/2018, folic acid, ethanol, octreotide, thiamine, and ascorbic acid syringes were also made in the ISO 5 Laminar Air Flow hood 4.

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OBSERVATION 8
Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, employees were observed donning re-used non-sterile laboratory coats/gowns and positioning them on top of the sterile hoods. Employees were observed entering the ISO 5 area with new and re-used non-sterile laboratory coats/gowns to produce sterile drug products. Furthermore, employees were observed donning sterile hoods and masks with their bare hands prior to the hand washing sanitization step in the ISO 8 anteroom. There is no assurance that the sterile gowning has not been contaminated due to the order of donning gowning apparel.

OBSERVATION 9
Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically, in the ISO 7 cleanroom, multiple ceiling tiles are not fully seated in their housing causing a gap into the area behind the housing and is not sealed.

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