

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Detroit District Office 300 River Place Suite 5900 Detroit, MI 48207 313-393-8100 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 5/22, 23, 24, 26/2017
	FEI NUMBER 3007957196

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Gregory M. Killmeier, Pharmacist

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

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

Observation # 1: Personnel were observed increasing the risk of contamination in the ISO 5 area.

Specifically,

On 05/22 - 24/2017, it was observed that the technicians' head and upper torso entered the ISO 5 area during the processing of TPN bags thereby exposing skin to the ISO 5 environment.

Observation # 2: Materials were observed increasing the risk of contamination in the ISO 5 area.

Specifically,

On 05/22 - 24/2017, the technicians were observed using non-sterile wipes in the ISO 5 area.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lindsey Schwierjohann	EMPLOYEE(S) NAME AND TITLE (Print or Type) Lindsey M. Schwierjohann, Investigator	DATE ISSUED 05/26/2017
	<small>Digitally signed by Lindsey Schwierjohann DN: cn=Lindsey Schwierjohann, ou=FDA, ou=People, email=Lindsey.Schwieerjohann@FDA.HHS.gov, o=U.S. Government, ou=FDA, ou=People, date=2017.05.26 08:37:18 -0400</small>		