

**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

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) (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, serial=20170526083718-0427, date=2017.05.26 08:37:18 -0400</small>		