

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  Minneapolis District Office 250 Marquette Avenue Suite 600 Minneapolis, MN 55401  Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	DATE(S) OF INSPECTION  7/10-14/2017
	FEI NUMBER  3013576855

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED  
 TO: Catherine M. Spencer, PIC/Team Leader/Clinical Pharmacist

FIRM NAME Heartland I.V. Care	STREET ADDRESS 1400 Energy Park Drive Suite 17
CITY, STATE AND ZIP CODE Saint Paul, MN 55108-5248	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drugs



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:

Sporicidal agents are not used in your facility's cleanrooms and/or ISO 5 area.

Specifically, while conducting a walk through and observation of your firm's compounding on 7/10/17, we noted that your facility does not currently use a sporicidal agent while cleaning the ISO 5 area. We noted that during the cleaning process (b) (4) was used to clean the ISO 5 area, followed by (b) (4).

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Anthony J. Ladner, CSO	DATE ISSUED  07/14/2017
	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) James K. Ireland, CSO	