

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/06-27/2017
	FEI NUMBER 3013442653

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew L. Farmer, Director of Pharmacy Operations

FIRM NAME Heartland Home Infusions, Inc. dba HHI Infusion Services	STREET ADDRESS 901 McClintock Drive, Suite 106
CITY, STATE AND ZIP CODE Burr Ridge, Illinois 60527	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.

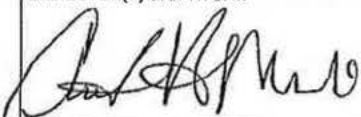
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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

Specifically, the firm does not use a sporicidal agent to clean the surfaces in the ISO 5 laminar flow hoods or the ISO 5 IV Room and ISO 6 Chemo Room floors, walls, and ceilings. The firm is required to use (b) (4) (b) (4) to clean the ISO 5 laminar flow hoods (b) (4) operations and (b) (4) work orders and the cleanroom floors (b) (4) with (b) (4). The (b) (4) cleaning of the ISO 5 laminar flow hoods and cleanrooms includes cleaning with (b) (4) solution. On 06/14/2016, viable air monitoring was conducted in the firm's facility. The ISO 6 Chemo Room sample location received out-of-compliance test results and Bacillus species were recovered from the sample. On 12/01/2016, viable air monitoring was also conducted in the firm's facility. The ISO 6 Chemo Room sample location received growth of microorganisms and Bacillus species were recovered.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Christina A. Miller, Investigator	DATE ISSUED 07/27/2017
--------------------------	--	---	-------------------------------

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 07/06-27/2017
	FEI NUMBER 3013442653

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew L. Farmer, Director of Pharmacy Operations

FIRM NAME Heartland Home Infusions, Inc. dba HHI Infusion Services	STREET ADDRESS 901 McClintock Drive, Suite 106
CITY, STATE AND ZIP CODE Burr Ridge, Illinois 60527	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

OBSERVATION 2

Beta-lactam drugs were produced without providing adequate containment, segregation, and cleaning of work surfaces and personnel to prevent cross-contamination. Specifically,

The firm produces both penicillin drug products and other sterile human drug products in (b) (4) laminar flow hood. On 07/06/2017, I observed the firm's sterile drug production technician produce the following products in (b) (4) laminar flow hood: Ceftriaxone 2gm in 20ml SWFI-IVP; Vancomycin 1.25gm in 250ml 0.9% NaCl; Meropenem 500mg in 100ml 0.9% NaCl and Oxacillin 2gm Q6hr (16g/300ml sterile water). The firm's current cleaning practice is to only use (b) (4) in the laminar flow hood (b) (4) different products, and (b) (4). On 07/06/2017, I observed the firm's technician produce Oxacillin 2gm Q 6hr (16g/300ml sterile water) which resulted in spillage of the finished drug product on the work surface. The technician only wiped down the work surface with (b) (4) after the completion of the work order. On 07/18/2017, I observed that the technician did not wipe down the laminar flow hood with any cleaning agent between work orders for sterile Vancomycin 1.5gm in 250ml 0.9% NaCl and Ceftriaxone 2gm in 100ml 0.9% NaCl.

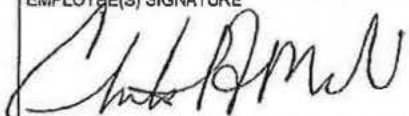
OBSERVATION 3

Non-microbial contamination was observed in your production area.

Specifically,

On 07/18/2017, I observed that the top metal ceiling grate in the ISO 5 laminar flow hood in the Chemo Room had a reddish-brown residue on the holes of the ceiling grate. This laminar flow hood is used for the production of sterile chemotherapy drug products.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Christina A. Miller, Investigator	DATE ISSUED 07/27/2017
--------------------------	--	---	---------------------------