

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Fax: (410) 779-5707 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 10/17/2016-10/25/2016*
	FEI NUMBER 3003432602

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. John A. Brandecker, Director

FIRM NAME Hunter Holmes McGuire Veterans Affairs Medical Center	STREET ADDRESS 1201 Broad Rock Boulevard
CITY, STATE AND ZIP CODE Richmond, VA 23224-4915	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products

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

OBSERVATION 1


The system for monitoring and maintaining environmental conditions in the aseptic processing areas was deficient. Specifically,

1. The differential pressure between the ISO 7 clean room (IV room) used to prepare non-hazardous drug products and ISO 7 anteroom on the 1st floor is not monitored.
2. There are no air returns in the clean rooms used to produce sterile drug products. The air returns are located in the adjacent anterooms and are located in the ceiling adjacent to the HEPA filters.

OBSERVATION 2

The system for cleaning and disinfecting the aseptic processing areas is deficient. Specifically, non-sterile disinfectants are used to disinfect surfaces, vials, and container/closures in the aseptic processing areas. For the initial cleaning, non-sterile wipes are used to disinfect the work surfaces in the ISO 5 hoods. Non-sterile wipes are also used for the initial wipe down of items such as vials, IV bags, and syringes that are brought into the ISO 5 hood.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Djamila Harouaka, Investigator	DATE ISSUED 10/25/2016
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* DATES OF INSPECTION
 10/17/2016(Mon), 10/18/2016(Tue), 10/25/2016(Tue)

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