

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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| DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6000 Metro Drive, Ste. 101 Baltimore, MD 21215 Tel: 410-779-5455 Fax: 410-779-5707 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 07/10/2018 - 07/19/2018* |
| | FEI NUMBER 3003432602 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: John A. Brandecker, MBA MPH, Medical Center Director

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| FIRM NAME Hunter Holmes McGuire Veterans Affairs Medical Center | STREET ADDRESS 1201 Broad Rock Blvd. |
| CITY, STATE AND ZIP CODE Richmond, VA 23224 | 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 (A) (B) (C) (D) (E) OBSERVED:

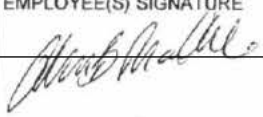
OBSERVATION 1

Environmental sampling conducted in the production area is deficient.

Specifically, low-mounted returns ^{HOB 2/19/18} ~~were~~ ^{was HOB 2/19/18} installed in the 5th floor ISO 7 anteroom, and subsequently recertified on 5/28/2018. However, no viable air or viable surface sampling, and no smoke studies, were performed as part of cleanroom recertification. Additionally (b) (4) sterile drug products were produced in the ISO 5 (b) (4) flow hood, located in the ISO 7 anteroom, from 5/29/2018 – 7/10/2018.

***DATES OF INSPECTION**

07/10/2018, 07/11/2018, 07/12/2018, 07/13/2018, 07/19/2018

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE  | EMPLOYEE(S) NAME AND TITLE (Print or Type) Helen B. Ricalde, Investigator | DATE ISSUED 7/19/18 |
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