

**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 2/19/2019-3/6/2019*
	FEI NUMBER 3011547221

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: James K. Gilman, Clinical Center CEO

FIRM NAME NIH Clinical Center Pharmacy Department	STREET ADDRESS 10 Center Drive, Building #10
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CITY, STATE AND ZIP CODE Bethesda, MD 20892-0001	TYPE OF ESTABLISHMENT INSPECTED Producer of sterile and non-sterile drug products
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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

Aseptic manipulations are performed in an area where the unidirectional movement of air in the ISO 5 area is disrupted.

Specifically, smoke studies completed in laminar airflow workbench (Equipment ID: LAFW2) on 10/10/2018 demonstrated that air refluxes around the control panel and where the sterile connections are made on the ExactaMix Compounder. The Compounder is used to prepare total parenteral nutrition (TPN) bags.

OBSERVATION 2

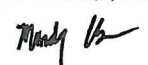

Deficiencies were noted with aseptic processing performed within the ISO 5 areas.

Specifically,

- (A) On 2/19/2019, an operator was observed reusing an alcohol prep pad that had come in contact with the ISO 5 biosafety cabinet (Equipment ID: BSC2) workbench surface and the chemo prep mat during the preparation of Tacrolimus Continuous Infusion, 5 mg/ml.
- (B) On 2/22/2019, operators were observed performing aseptic processing in ISO Class 5 laminar airflow workbench (Equipment ID: LAFW1) with part of the non-sterile gown around the abdomen area inside the ISO 5 work surface.
- (C) On 2/22/2019, an operator was observed resting her gloved hands on the work surface of LAFW1 during preparation of Bone Marrow Pink Syringes (not administered in humans). During the operation, the technician was observed to rest one hand at a time directly on the ISO 5 work surface and use the other hand to hold the barrel of a syringe. The operator's arm was also observed to pass over the open bottle of DMEM (Dulbecco's modified eagle medium).

OBSERVATION 3

Cleaning pads used in the ISO 5 classified aseptic processing areas were not sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE  	EMPLOYEE(S) NAME AND TITLE (Print or Type) Mindy M. Chou, Investigator Djamila Harouaka, Microbiologist	DATE ISSUED 03/06/2019
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

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Specifically,
 (A) EasyReach Cleaning Pads (Part # MEQT0001) used to clean the interior surfaces of the ISO 5 hoods are not sterile.
 (B) On 2/19/2019, resealable multi-packs of Prosat® Sterile Presaturated Wipes were found stored with the seal open in the ISO 7 area. The Prosat® Sterile Presaturated Wipes are used in the routine cleaning and disinfection of the ISO 5 hoods. The presaturated wipes are also used to disinfect materials or supplies before introduction into and use in the critical ISO 5 zone.

OBSERVATION 4

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, the media fills are performed using the CHEMOTEQ kit, which fails to simulate preparation of the total parenteral nutrition (TPN) bags using the ExactaMix Compounder. TPN preparations represent the largest volume parenteral drug products made at the site.

OBSERVATION 5


Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, materials are transferred into and out of the ISO 7 Sterile IV Prep Room (1C166A5B) using two cart pass-throughs. On 2/22/2019, it was observed that the door to the pass-through (labeled 'IN' in room 1C166A5B) would move when the door to the second pass through (labeled 'OUT' in room 1C166A5B) was forcefully shut in the ISO 8 IV Prep Anteroom (1C166A5A). On 2/25/2019, the door sweeps on the cart pass through doors in the ISO 8 IV Prep Anteroom (1C166A5A) showed signs of damage and were secured to the door using cleanroom tape.

OBSERVATION 6

The material of construction of the cleanroom walls is not suitable for the intended use.

Specifically, on 2/19/2019, several pieces of tape were observed on the walls or ceiling of the ISO 7 Sterile Hazardous Prep

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Room (1C166A7B), the ISO 7 Immunotherapy Prep Room (1C166A7D), and the ISO 7 Sterile IV Prep Room (1C166A5B). The tape is used to identify areas where the paint is flaking or paint bubbles or other damage to the walls, door, or other surfaces. According to management, structural damage to the facility is repaired approximately every two to four weeks.

Between 1/18/2019 and 2/25/2019, 66 locations were identified by the pharmacy staff that required repair. Sixty-four of the identified locations were in the ISO classified rooms of the I-IVAU.

OBSERVATION 7

Your facility was designed and/or operated in a way that permits poor flow of personnel.

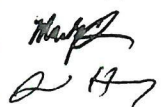
Specifically, sinks located in the ISO 8 IV Prep Anteroom (1C166A5A) and ISO 8 Gowning Room (1C166A7A) were operated in a manner that allowed water to pool along the sink or on the floor adjacent to the sink.

(A) On 2/19/2019 during the facility walkthrough, a puddle of what appeared to be water (approximately 10 centimeters in diameter) was observed on the floor of the ISO 8 IV Prep Anteroom (1C166A5A) adjacent to the sink. Furthermore, on 2/19/2019, a pharmacist was observed scrubbing in at the sink in ISO 8 IV Prep Anteroom (1C166A5A) then donned the gown which contacted the ISO 7 IV Prep Gowning Room (1C166A5A1) floor.

(B) On 2/22/2019, standing water was observed under a piece of tape on the backsplash panel of the sink located in the ISO 8 IV Prep Anteroom (1C166A5A). Water also appeared to be pooled beneath a bottle of hand sanitizer and nail cleaners placed on the ledge above sink.

(C) On 2/19/2019 and 2/22/2019, standing water was observed to have pooled along the right side of the sink in the ISO 8 Gowning Room (1C166A7A). Water was also seen beneath a bottle of nail cleaners and the Hibiclens bottle next to the faucet.

***DATES OF INSPECTION**
 2/19/2019 (Tue), 2/20/2019 (Wed), 2/21/2019 (Thu), 2/22/2019 (Fri), 2/25/2019 (Mon), 2/28/2019 (Thu), 3/01/2019 (Fri), 3/06/2019 (Wed)

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