DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax:(407) 475-4768 Industry Information: www.fda.gov/oc/industry	05/12/2014 - 05/23/2014* FEI NUMBER 3010810839

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Paul Wayne Franck, Owner

FIRM NAME	STREET ADDRESS
Franck's Lab Inc dba Trinity Care Solutions	202 SW 17th Street Suite C
CITY, STATE, ZIP CODE, COUNTRY Ocala, FL 34471	TYPE 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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient in that walls are not smooth and/or hard surfaces that are easily cleanable.

Specifically, we observed the following conditions for walls and ceilings in your ISO 7 clean room:

A. The impact of recent and ongoing remodeling on airflow in your ISO 7 clean room has not been assessed and you have not performed a risk assessment to determine the impact of this ongoing construction's potential for product contamination. This construction began on or about the beginning of May 2014 and includes the construction of an adjacent chemotherapeutic room with a new door. On 5/12 and 5/13 we observed that the magnehelic gauge that measures the positive pressure from your ISO 7 clean room to your ISO 8 ante-room was at or close to zero pressure. Your environmental monitoring of the positive pressure between the two rooms was documented in your (b) (4) Quality Compliance Report as within normal limits. From 5/1-2/2014 you have processed (b) (4) prescriptions or approximately (b) (4) doses for the following sterile compounded products: Cefepime 2gm/100ml 0.9% NS (b) (6), Vancomycin 900 mg/100ml 0.9% NS (b) (6), Meropenem 1 gm/100 ml 0.9% NS (b) (6), Cubicin 543 mg/100 ml 0.9% NS (b) (6), Cefepime 2 gm/100 ml D5W (b) (6), Primaxin 500 mg/100 ml 0.9% NS (b) (6), Invanz 1gm/100 ml 0.9% NS (b) (6), Unasyn 1.5 gm/100 ml 0.9% NS (b) (6), Cubicin 700 mg / 100ml 0.9% NS (b) (6), Ceftriaxone 1 gm/50ml D5W (b) (6), Vancomycin 750 mg/100 ml 0.9% NS (b) (6), Ceftriaxone 1gm/150 ml 0.9% NS (b) (6), Vancomycin 750 mg/150 ml 0.9% NS (b) (6), Cefepime 1 gm/50 ml D5W (b) (6), Vancomycin 1500 mg/300 ml D5W (b) (6) Impenam/Cilastin 500mg/100 ml 0.9% NS (b) (6), Vancomycin 1.75 gm/200 ml D5W (b) (6), Ceftazidime 1 gm/100 ml 0.9% NS (b) (6), Cefazolin 6 gm/300 ml 0.9 % NS (b) (6), Cefazolin 2 gm/100 ml 0.9% NS (b) (6), Vancomycin 4 gm/500ml 0.9% NS (b) (6), Cubicin 600 mg/100 ml 0.9% NS (b) (6), Invanz 1 gm /100 ml 0.9 % NS (b) (6), Mezopenem 1 gm/100 ml 0.9% NS (b) (6).

B. The area around the ground level aluminum vent placed below and behind the (b) (4) Laminar Flow hood is not smooth and easily cleanable. This material appears to be either particle board or cardboard and is a potential source of viable and non-viable particles in your ISO 7 clean room. Your environmental monitoring procedures do not include viable and non-viable particle counts. Although section D of your procedure "PE001: QUALITY CONTROL OF THE CLEAN ROOM COMPLEX" (revised 2011) requires "Before (b) (4) the class-100 and gowning room will be tested for particle counts using (b) (4)", your facility does not own a (b) (4), and particle counts (viable and/or non-

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viable) have not been performed since September 12, 2013, 8 months prior to this inspection.

C. Ceiling tiles in the ISO 7 clean room and the ISO 8 ante-room are not sealed, also in the ISO 7 clean room there were visible tears in two ceiling tiles, including one tile made of porous material inappropriate for a clean room.

D. We observed flaking paint and rust on the front edge of the bench of the ISO-5 laminar flow hood, at waist-height, in position, which may touch the technician's gown during compounding of IV drugs.

OBSERVATION 2

Buildings used in the manufacture, processing, packing or holding of drug products are not maintained in a clean and sanitary condition and free of infestation by rodents, birds insects, and other vermin.

Specifically, we observed that the ISO 7 clean room contained inappropriate items such as a radio, computer monitor, consumable supplies contained in cardboard boxes, a piece of wood for leveling the laminar flow hood, a hand held calculator, pens and paper without plastic cover. We also observed the presence of dead insects on the light panel in the ceiling directly above the ISO 5 Nuaire laminar flow hood as well as above the ante-room area where the non-sterile garments are stored and donned and the sink where processing employees prepare for sterile processing.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically, while in a staging room with no air quality (ISO) classification, your pharmacy technician was observed opening the manufacturer's protective cover around the elastomeric infusion devices using bare hands, prior to performing hand washing/gowning procedures, and then placed them in a plastic tote without a sanitization step, and into a pass-through window to the ISO-8 ante-room. After hand washing and partial gowning (without gloves), these elastomeric infusion devices were then transferred with bare hands into a second plastic tote. After donning sterile gloves, these elastomeric infusion devices were then transported to the ISO-7 clean room and placed onto the ISO-5 processing bench location without a sanitization step. These elastomeric infusion devices were then filled with 0.9% normal saline and reconstituted Vancomycin 1gram lot # (b) (4). The Pharmacy Work Order for the Vancomycin 1 gm /100 ml 0.9% NS under Rx # (b) (6) does not include compounding instructions applicable to the operations performed and does not provide written instructions covering proper aseptic technique for this sterile processing.

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OBSERVATION 4

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, you are cleaning your ISO 5 surfaces only with [redacted] (b) (4) You are not also using a cleanser or a sporicidal disinfectant to reduce and remove a broader spectrum of microorganism and you have conflicting written work instructions that do not specify which surfaces and objects should be cleaned with which type of sanitizer such as bleach, sterile 70 % alcohol, Quat 2, Tergisyl, or Tex-Q.

A. One procedure said to be in use includes instructions on how to prepare a [redacted] (b) (4)

B. The written procedure PE 008: MAINTENANCE OF CLEAN ROOM revised 2011 does specify a [redacted] (b) (4) ppm solution; it does not explain the calculation.

C. You provided two conflicting versions of procedure PE 008: MAINTENANCE OF CLEAN ROOM one from 2011 and one from 2009. The 2009 version of this procedure includes instructions to prepare a solution that is too weak for clean room sanitation and the instructions in sections IV 2.d and IV 3.b state, [redacted] (b) (4)

D. Your bottle of [redacted] (b) (4) disinfectant (non-sporicidal, in use for shelves, bins, carts, etc. in the ISO-7 IV compounding and ISO-8 ante-room) was over one year past its expiration date. Manufacturer's expiration, "Exp. 04/2013" was printed on the spray bottle of ready-to-use/pre-mixed [redacted] (b) (4) solution.

OBSERVATION 5

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically, the laminar flow hoods located in the ISO 7 clean room have been relocated to accommodate the addition of a second door. The [redacted] (b) (4) laminar flow hood is now located directly under your two HEPA filter vents and appears to potentially obstruct the unidirectional air flow. The ISO 7 clean room has not been qualified under these new conditions and

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your most recent qualification was not performed under dynamic (in use) conditions and no smoke study video was available. Additionally, your HEPA filter air handling system's "on/off" function is controlled by an unlabeled, uncovered, regular wall switch near a tabletop used for supply preparation. With no cover on the switch and no controlled access to the supply room it's located in, there is a risk that an employee or contractor could inadvertently, unknowingly turn the system off.

OBSERVATION 6

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, your pharmacy technician was observed wearing non-sterile hair nets, shoe covers, and a disposable lab coat in the ISO 7 clean room directly in front of the ISO 5 processing laminar flow hood during the infusion compounding of Vancomycin 1gram lot # [redacted (b) (4)] into [redacted (b)] elastomeric infusion devices to achieve a Vancomycin 1 gm/100 ml 0.9% NS Rx # [redacted (b) (6)].

*** DATES OF INSPECTION:**
05/12/2014(Mon), 05/13/2014(Tue), 05/14/2014(Wed), 05/15/2014(Thu), 05/16/2014(Fri), 05/23/2014(Fri)

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