

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER  4040 N. Central Expressway Dallas TX 75204 214-253-5200	DATE(S) OF INSPECTION 07/25-08/02/2017
	FEI NUMBER 3005011132

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

**TO: John Glynn, Chief Financial Officer**

FIRM NAME First Call Pharmacy, LLC	STREET ADDRESS 1500 Veterans Memorial Blvd.
CITY, STATE AND ZIP CODE Kenner, LA 70062-5386	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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 OBSERVED:

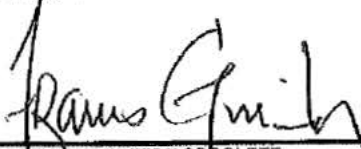
On 07/25/2017, I observed the procedures that were used to aseptically produce 14/1gm and 8/1.5gm doses of Vancomycin, and on 07/26/2017, I observed the procedures that were used to aseptically produce 10/1gm, 14/1.5gm, and 14/2gm doses of Vancomycin (Lot# 753653A). I also observed the procedures that were used to aseptically produce 7/2gm doses of Ceftriaxone on 07/25/2017 and 07/26/2017 each (Lot# 720068M).

**OBSERVATION 1**

Personnel engaged in aseptic processing were observed with exposed hands. Specifically, on 07/25/2017, I observed a sterile production technician with her bare hands exposed inside of an ISO 5 (b) (4) laminar airflow hood as she donned gloves. Another adjacent sterile production technician was engaged in sterile production procedures at that same time.

**OBSERVATION 2**

Personnel engaged in aseptic processing were observed with exposed mouth. Specifically, on 07/25/2017, I observed a sterile production technician communicating with the pharmacist-in-charge as he (the pharmacist-in-charge) stood behind the line of demarcation on the dirty side of the Ante Room. The sterile production technician was standing in the ISO 7 sterile production room (containing the ISO 5 (b) (4) laminar airflow hoods), holding the door between the ISO 7 sterile production room and the Ante Room opened with one hand, while holding her face mask down below her chin as she talked. The sterile production technician returned to the sterile production room and resumed performing various procedures in the production room without first sterilizing her gloved hands.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Francis Guidry, Investigator	DATE ISSUED 08/02/2017
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DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

**OBSERVATION 3**


Personnel engaged in aseptic processing were observed with exposed skin, hair, and "street clothes." Specifically, during the inspection, I observed two sterile production technicians aseptically producing sterile drug products while wearing ill-fitting protective garments and hair nets that resulted in the exposure of hair, skin, and their "street clothes" in the ISO 7 sterile production room. I observed both sterile production technicians leaning into the ISO 5 (b) (4) laminar airflow hoods, repeatedly breaking the plane of containment, exposing hair, skin, and their "street clothes" in the ISO 5 (b) (4) laminar airflow environment as they performed sterile production procedures.

**OBSERVATION 4**

The facility is designed and/or operated in a way that permits poor flow of materials. Specifically, during the inspection, I observed the use of a pass through window located between the ISO 7 sterile production room (containing (b) (4) ISO 5 (b) (4) laminar airflow hoods) and an uncontrolled office and raw material storage area. That pass through window was being used to supply the processing area with materials and supplies. I did not observe the materials and supplies to be sanitized before being placed in the pass through window and being handled by sterile production technicians.

**OBSERVATION 5**

The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent. Specifically, the cleaning/sanitizing procedure you use to guard against the contamination of the sterile products you aseptically produce is not adequate. Work surfaces, walls, ceilings, and floors are cleaned and sanitized (b) (4) on a (b) (4) basis, with (b) (4) which is reportedly sporicidal, and (b) (4) which is not. Only (b) (4) was observed in use during the inspection.

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