DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	03/30/2015 - 04/09/2015* FEI NUMBER 3002401385

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mark W. Shinabery, Owner/Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Custom Compounding Center	11700 Kanis Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Rock, AR 72211-3745	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically,

A. On 03/31/2015, your firm's Owner/Pharmacist-in-Charge stated your firm failed to adequately certify methods and processes used for the production equipment, (b) (4) (b) (4) (ID # (b) (4)) and the (b) (4) (b) (4) (ID # (b) (4)) used in the depyrogenation and sterilization of production glassware and (b) (4) .

B. On 03/30/2015, your firm's Owner/Pharmacist-in-Charge stated your firm failed to validate any of the processes used to render produced drugs sterile. For example, during the production of Avastin (NDC # 500242-0060) your firm failed to validate the repackaging operation which is used to render a non-sterile component sterile for the Supplier Lot # (b) (4) /your firm's Lot # 03302015+4264@8.

C. On 03/30/2015, during our walkthrough of your facility's Cleanroom # (b) (4) Chemotherapy room (ISO 7 Classified), we observed your Pharmacy Technician exhibiting poor aseptic techniques in that:

1. Your firm's Pharmacy Technician was observed leaning forward, with (b) (6) elbows covering the ventilation grid inside the (b) (4) (Model # (b) (4) , S/N (b) (4)) ISO 5 Classified (b) (4) while repackaging Avastin (NDC # 500242-0060), Supplier Lot # (b) (4) /Firm's Lot # 03302015+4264@8.
2. Your firm's Pharmacy Technician was observed leaving the ISO 5 classified (b) (4) where she was repackaging Avastin (NDC # 500242-0060), Supplier Lot # (b) (4) /Firm's Lot # 03302015+4264@8, entering the ISO 7 classified Ante-room and Powder room to perform a task, only to return, spray the existing gloves with (b) (4) and return to processing the current batch of product. Your technician failed to change gloves.

OBSERVATION 2

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically,

A. Your firm failed to adequately validate the following sterile and non-sterile drug production areas currently

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	Camerson E. Moore, Investigator Jason R. Caballero, Investigator	04/09/2015

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classified by your firm as an ISO 7 in the dynamic state: Cleanroom (b)(4) (sterile production room, positive pressure), Cleanroom (b)(4) (chemotherapy room, negative pressure), Anti-room (positive pressure), and Powder room (positive pressure) in the prevention of contamination in the dynamic condition.

B. On 03/30/2015, we observed three Magnehelic gauges on the exterior wall of the Powder Room (ISO 7 classified) leading to cleanroom areas failed to physically measure generated and maintained differential pressures levels in both static and dynamic states.

OBSERVATION 3

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

Specifically,

A. During a review of your firm's 2014 - 2015 Environmental Monitoring, (b) (4) Analysis, smoke pattern studies, for sterile and non-sterile drug production ISO 5 Classified (b) (4) (Sterile - (b) (4) Model # (b)(4) (b) (4) S/N (b) (4) and Non Sterile - (b) (4) , S/N (b) (4)), your firm failed to perform these studies in the dynamic state. On 4/1/2015, your firm's Owner/Pharmacist-in-Charge stated all smoke studies were completed in the (b) (4)

B. On 03/30/2015, we observed your firm's weigh scales in the Powder Room (ISO 7 classified) are environmentally exposed without adequate containment to prevent powder particulate cross-contamination of drug products during admixing.

C. Your firm failed to define a written control system for the plastic slated doors leading into all ISO classified areas to prevent drug product contamination.

OBSERVATION 4

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically,

A. Your firm failed to require adequate protective apparel to protect drug products from contamination. For example your firm's Pharmacy Technician was observed having facial and neck areas exposed during the repackaging of Avastin (NDC # 500242-0060), Supplier Lot # (b) (4) /Firm's Lot # 03302015+4264@8 1.25mg/0.05ml syringes.

B. Your firm fails to require use of sterile hair nets and face masks during the production of sterile drug products.

C. Your firm fails to require the continuous use of sterile gowning during the production of sterile drug products. For example on 3/30/2015, a sterile gown used by your firm's Pharmacy Technician was observed hanging on the corner of a stainless steel shelving located in the ISO 7 Classified Ante-room. Your firm's procedure, Room Cleaning Procedures-Compounding Labs-Sterile & Non Sterile (SOP # 5.005, Implemented date 9/19/14), reports shelving cleaning occurs only (b) (4) . Your firm reuses a single gown an entire drug production day.

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OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, on 03/30/2015, your firm's Owner/Pharmacist-in-Charge stated your firm failed to have a written stability program for all sterile and non-sterile drug products.

OBSERVATION 6

Representative samples are not taken of each shipment of each lot of components for testing or examination.

Specifically, on 03/30/2015, your firm's Owner/Pharmacist-in-Charge stated your firm failed to have a written procedure for receiving, inspecting, and accepting lots of non-sterile components utilized in the production of sterile finished drug products.

* **DATES OF INSPECTION:**
03/30/2015(Mon), 03/31/2015(Tue), 04/01/2015(Wed), 04/02/2015(Thu), 04/03/2015(Fri), 04/09/2015(Thu)

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