DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax:(615) 366-7802 Industry Information: www.fda.gov/oc/industry	09/14/2015 - 10/27/2015
	FEI NUMBER 3011469631

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Charles R. Bell, Founder and President, COO

FIRM NAME	STREET ADDRESS
Advanced Infusion Solutions	132 Fairmont St Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Clinton, MS 39056-4721	Producer of Sterile 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 I OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- On 1/15/2015, air and surface samples collected and analyzed by Hayes Microbial Consulting found multiple organisms of bacteria and fungus in your ISO 5 and ISO 8 areas. Your firm did not provide sufficient evidence indicating these areas are free of microbial contamination prior to your firm beginning operations at this facility on 2/9/2015.

- Your firm's management states it performs surface and air monitoring in the ISO 5, ISO 7, and ISO 8 areas weekly. This is inadequate as environmental conditions are not performed each day sterile drug products are produced. In addition, the documentation provided by your firm indicates Bond Pharmacy did not start in-house environmental monitoring until on or about 7/30/2015, more than 5 months after your firm started production.

- On 9/14/2015, gaps were observed around the perimeter of the pass through door from an unclassified area leading into the ISO 7 area.

- According to your firm's SOP, AIS-PHA-408: "Gloved Fingertip Sampling", all new compounding personnel (compounding technicians, as well as, all pharmacist, regardless, of whether they physically perform the duties of compounding or they supervise compounding) must successfully complete 3 Gloved Fingertip sampling occurrences prior to compounding CSPs for human use. For low/medium risk level compounding, subsequent gloved fingertip sampling will occur annually.
  - Documentation provided by your firm indicates one pharmacy technician completed gloved fingertip sampling on 10/20/2015, 8 1/2 months after your firm became operational on 2/9/2015. Furthermore, on 9/14/2015, I observed 2 pharmacy technicians in your facility, only one pharmacy technician completed gloved fingertip sampling on 10/20/2015.

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	June P. Page, Investigator Marvin P. Jones, Investigator	10/27/2015

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OBSERVATION 2

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

Specifically,

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.5 describes hand washing will be performed for at least 30 seconds.
  - On 9/14/2015, a pharmacy technician was observed washing their hands in anteroom for approximately 10 seconds and drying their hands with a non-sterile disposable cloth.

- According to your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.4.9, gloved hands will be sprayed with sterile 70% IPA prior to entering the ISO 5 area and anytime the employee's hand re-enters the ISO 5 area.
  - On 9/14/2015, a pharmacy technician was observed placing the outer covering of a 0.9% NaCl 1000-mL bag into the trash receptacle in the ISO 7 area and returning to the ISO 5 area without sanitizing their gloves.

OBSERVATION 3

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

Specifically,

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing", section 4.3.8 states to don a clean, lint free cover garment (Tyvek or equivalent) with sleeves that fit snugly around the wrists and which securely encloses the neck. In addition, section 4.3.10 of the aforementioned SOP, states to fasten the closures of the gown completely.
  - On 9/14/2015, a pharmacy technician was observed wearing a non-sterile gown that was open, exposing their street clothes to the sterile environment.

- Per your firm's SOP, AIS-PHA-404: "Hand Hygiene and Garbing" , section 4.5.1.3, gowns may be saved for subsequent use during the same shift/day and must be hung on a hook on the clean side of the anteroom.
  - On 9/14/2015, a pharmacy technician was observed dragging their gown on the floor of the anteroom from the clean side to the dirty side and then hung up the gown on the dirty side of the anteroom to be reused.
  - On 9/14/2015, another pharmacy technician was observed entering the anteroom from the buffer room, and then hung their gown on the dirty side of the anteroom for subsequent use.

- The gowning components your firm uses during aseptic processing are not sterile. The gowns, hair covers, face masks, and shoe covers are stored in an unclassified area. Furthermore, the gowns are stored in an open bag.
  - On 9/14/2015, a pharmacy technician was observed without a beard net and no eye protection while processing in the ISO 7 and ISO 5 areas.

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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,

- In the ISO 7 area (Buffer Room), rust spots were observed on floor, ~~and filth~~ and residue streaks were observed on the walls. Your ISO 7 area is adjacent to your firm's ISO 5 area, where production occurs. Furthermore, no physical barrier distinguishes your firm's ISO 7 area from the ISO 5 area.

- According to the SOP, AIS-PHA-304: "Cleaning and Disinfecting of the Compounding Facility", cleaning will be performed in the ISO 5 area (VLAFW) prior to the beginning of each shift, immediately prior to each batch, every 30 minutes throughout the shift when ongoing drug production activities are occurring, after spills, and when microbial contaminations known to have been or is suspected of having been introduced.
    - Your firm provided a sample of the cleaning log for 9/14/2015 and a sample log from 7/10-16/2015 which shows daily cleaning only occurs at the beginning and end of the day.

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