**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<br>Nashville, TN 37217-2597<br>(615) 366-7801 Fax:(615) 366-7802<br>Industry Information: www.fda.gov/oc/industry | 09/15/2015 - 10/27/2015<br>FEI NUMBER<br>3011804748 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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

| FIRM NAME | STREET ADDRESS |
|---|---|
| Bond Pharmacy, Inc. dba Advanced Infusion Solutions | 623 Highland Colony Pkwy Ste 100 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Ridgeland, MS 39157-6077 | 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 WE OBSERVED:**

## OBSERVATION 1

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

Specifically,

- On or about 7/10/2015, air and surface samples were collected and analyzed by Hayes Microbial Consulting. Results of these samples identified multiple organisms of bacteria and fungus in your firm's ISO 7 and ISO 8 areas. Your firm failed to conduct appropriate follow-up investigations. Your firm failed to provide documentation identifying the organisms or species for each colony growth.
  - On 7/17/2015, Hayes Microbial Consulting reported 6 air samples and 2 contact sample exceed, or found to be equal to, the limit of detection (1 CFU/M3):
    - An air sample was taken at location #37: Bacteria: Bacillus, Corynebacterium, Micrococcus, and Staphylococcus sp. were detected, exceeding the prescribed action level set forth in your firm's SOP, AIS-PHA-210: "Pharmacy Cleanroom Viable Air Sampling". The ISO 7 action level is >10, the Hayes microbial Consulting report documents 12 CFU's was recorded.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #37 is in the middle of your firm's gown room (ISO 7 area).
      - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
        - Your firm's in-house report indicates sampling occurred on the far W and E side of the gown room (ISO 7 area). This sampling location is not equivalent to sampling location #37 conducted by Hayes Microbial Consulting.
    - A contact sample was taken at location #46: Bacteria: Staphylococcus sp. was detected.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #46 is your firm's staging area (ISO 8 area).
        - Your firm's documentation supporting in-house environmental contact plate sampling indicates sampling was not conducted in your firm's staging area.
    - A contact sample was taken at location #40: Bacteria: Staphylococcus sp. was detected.
      - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #40 is in the firm's anteroom - on the NE side of the door entrance

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from the unclassified area (ISO 8 area).

- Your firm's documentation supporting in-house environmental contact plate sampling indicates 3 sampling locations occurred on the SW side of the anteroom while 0 (zero) samples were taken on the NE side of the anteroom. These sampling location are not equivalent to sampling location #40 conducted by Hayes Microbial Consulting.

- An air sample was taken at location #35: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #35 is your firm's stock solution room (ISO 7 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's in-house report documents zero colonies were detected at location (5A) LAFW 40647 - Stock Solutions Room (ISO 5 area) and zero colonies were detected at location (4A) Stock Solutions Room. Your firm's in-house environmental monitoring locations was compared to your firm's 3rd party contractor's environmental monitoring locations. Upon comparison, it appears your firm's sampling location are not equivalent to the sampling location #35 conducted by Hayes Microbial Consulting.
- An air sample was taken at location #39: Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. were detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #39 is in the middle the firm's anteroom (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's in-house report documents colony growth, 32 CFU's, in the ISO 8 anteroom - gown room door (ISO 8 area). This sampling location is not equivalent to sampling location #39 conducted by Hayes Microbial Consulting.
- An air sample was taken at location #41: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #41 is your firm's cart pass thru area (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.
- An air sample was taken at location #43: Bacteria: Staphylococcus sp. was detected.
  - According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #43 is your firm's materials handling area (ISO 8 area).
  - On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
    - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.
- An air sample was taken at location #45: Fungi: Cladosporium, unspecified mold. Bacteria: Bacillus, Micrococcus, and Staphylococcus sp. were detected.

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- According to the pharmacy cleanroom room layout located in the Controlled Environment Performance Test and Certification Report, location #45 is your firm's staging area (ISO 8 area).
- On 7/17/2015, your firm conducted in-house environmental air sampling, which was entered into your firm's in-house report, Simplifi 797.
  - Your firm's 7/17/2015 in-house report does not document sampling was conducted at this location.

- Your firm's environmental monitoring data from July - October 2015, documents several instances indicating colony growth in your firm's ISO 5, ISO 7, and ISO 8 areas. However, your firm did not conduct adequate investigations assuring these areas are free from microbial contamination.

- Surface and air monitoring of the ISO 5 environment are not performed each day sterile drug products are produced. Your firm's current practice is to perform weekly surface and air monitoring. This is inadequate as environmental conditions are not monitored every day production occurs.

- Personnel monitoring is not performed each day sterile drug products are produced.

- Your firm's management stated in-house personnel monitoring is performed weekly. However, management did not provide documentation assuring your firm conducted personnel monitoring prior to the beginning the production of sterile drug products on 2/10/2014 through 6/4/2015.

- 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 high risk level compounding, subsequent gloved fingertip sampling will occur semi-annually.
  - On 9/15/2015, I observed 2 stock solution pharmacists actively compounding stock solutions of 6 - 600mL bags of Morphine 62.5 mg/mL and 5 - 200mL bags of Fentanyl 10 mg/mL. Your firm did not provide personnel monitoring data for the stock solution pharmacist for 2015.
  - In addition, your firm did not provide documentation supporting fingertip monitoring was conducted for all pharmacists I observed actively compounding in your facility on 9/15/2015.

**OBSERVATION 2**

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

Specifically,

- On 9/15/2015, a HEPA filter (ISO 5 area) appeared dirty; a thermaplate (ISO 7 area) used for compounding appeared

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dirty; several storage bins containing sterile components, located directly under the ISO 5 hood, appeared to have residue from splatter or spills; a trash receptacle (ISO 7 area) appeared dirty.

- On 9/15/2015, a stock solution compounding pharmacist was observed improperly cleaning the LAFW prior to performing aseptic bulk compounding of fentanyl. The pharmacist sprayed 70% Sterile IPA directly on a sterile disposable cloth and wiped the workbench in a circular fashion, moving from front to back.

**OBSERVATION 3**

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,

- Your firm's SOP, AIS-PHA-412: Conduct of Personnel in Controlled Areas and Aseptic Technique Overview, section 7.12 states Area Clearance: is an activity that ensures that only one "batch" is present at a compounding workstation to avoid error and mix-ups of the components and labels from which the CSP is being prepared.
  - On 9/15/2015, a pharmacist was observed pulling from 7 different stock medications in one ISO 5 hood.
  - On 9/15/2015, multiple unlabeled syringes from different stock solutions, for multiple patients, were observed lying on a cart waiting to be compounded.
  - On 9/15/2015, multiple pharmacists were observed holding two separate prescriptions for two different patients, all syringes are unlabeled.
  - On 9/15/2015, powdered APIs were observed being weighed and staged, uncovered, in the ISO 7 area. The unlabeled, uncovered powder APIs were placed on a staging cart with multiple unlabeled syringes before being brought to the ISO 5 area.
  - On 9/15/2015, we observed multiple unlabeled compounded patient specific medications were placed in a hot water bath.

**OBSERVATION 4**

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

- Your firm's stock solutions undergo endotoxin testing one time prior to processing. However, your stock solutions are punctured multiple times during processing over several days. Your firm's stock solutions, at time of use, is not representative of the endotoxin testing conducted prior to processing.

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## OBSERVATION 5

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

Specifically,

- On 9/15/2015, a pharmacist was observed crossing into the clean side of the anteroom with no shoe cover over their street shoes.
- On 9/15/2015, a pharmacist was observed reaching under the ISO 5 workbench to gather supplies to continue aseptic processing 24 times without sterilizing their gloves or the components entering ISO 5 area form a dirtier area.
- On 9/15/2015, a pharmacist compounding a stock solution of fentanyl was observed leaving the ISO 5 area, entering the ISO 7 area, and returning to the ISO 5 area 13 times before sanitizing their gloves.
- On 9/15/2015, multiple pharmacists were observed with their heads under the ISO 5 hood.

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