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	12/01/2014 - 12/22/2014 FEI NUMBER 3011123993

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jeffrey S. Steele, 50% Owner, President, & Pharmacist

FIRM NAME	STREET ADDRESS
Infusion Systems of SW Florida Inc. dba Myerlee Pharmacy	1826 Boy Scout Drive
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Myers, FL 33907	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:

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. For the following three out of three products I reviewed, (b) (4) is not performed for each production run:
   1. Human Chorionic Gonadotropin (2,000 IU/vial)
   2. Super MICCC (Methionine 25 mg, Inositol 50 mg, Choline 50 mg, Chromium 200 mcg, & Cyanocobalamin 700 mcg/ml)
   3. Testosterone Cypionate (200 mg/mL)

B. The dry heat depyrogenation and (b) (4) have not been validated. In addition, there are no written calibration procedures or actual calibration documentation available for these pieces of equipment. This includes lack of (b) (4) documentation for the temperatures being used.
   1. The (b) (4) is used for all glassware that comes into direct contact while preparing sterile drug products.
   2. The (b) (4) is used for finished product vials and rubber vial stoppers used in the filling of sterile drug products.

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OBSERVATION 2

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

Specifically,

A. I observed the following aseptic deficiencies during the preparation of sterile drug products:
   1. Personnel were not sanitizing items (e.g., bags containing vials, syringes, and (b) (4) prior to placing them into the laminar flow hood (ISO 5).
   2. Personnel were resting their forearms inside the laminar flow hood while preparing sterile drug products.
   3. Personnel did not put on sterile gloves prior to entering the Buffer room; instead, they put on non-sterile gloves. They then removed their non-sterile gloves inside the laminar flow hood and exposed their bare hands inside the laminar flow hood while donning sterile gloves.
   4. Personnel were observed not sanitizing gloves with (b) (4) periodically during sterile drug preparation operations.
   5. Your bare skin (forearms) was exposed under the laminar flow hood while preparing sterile drug products, because your gown did not appropriately fit.

B. The media fills documented as being conducted by your pharmacists and technicians within the Buffer room and under the laminar flow hood were found to be deficient in that they do not accurately simulate current production processes and conditions that represent the most stressful/challenging conditions and optimize detection of any microbiological contamination. For example, there is no media fill data for your current operation of filling over (b) glass Human Chorionic Gonadotropin vials (5 mL) for a prepared batch that uses (b) (4) glass vials, stoppers, caps that are sterilized (b) (4).

OBSERVATION 3

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

Specifically,

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A. Air (viable and non-viable) sampling within all classified areas is not performed during daily operations. You stated that sampling is only performed every (b) (4) under non-dynamic conditions.

B. There is no continuous or at least periodically monitoring of air pressure differentials during production from the buffer room and ante room to the surrounding non-classified pharmacy area.

C. For all classified areas, you said that the following was not conducted:
   1. Air flow measurements under dynamic conditions.
   2. Dynamic airflow pattern studies (i.e., smoke studies) in the laminar flow hoods inside your Buffer rooms.

D. Surface sampling within all classified areas is not adequate based on the following:
   1. Surface sampling within your laminar flow hoods is not conducted during daily operations. In the last 6 months, only (b) (4) work surface sample was taken from the (b) (4)
   2. Surface sampling was not conducted during certification of all the classified areas. You stated that sampling is only conducted at (b) (4) location every (b) (4) at the (b) (4)

E. Personnel monitoring within all classified areas is not adequate based on the following:
   1. Personnel monitoring (e.g., fingertip sampling) is not conducted during daily operations. You stated that sampling is only conducted every (b) (4)
   2. Your personnel's gowning materials have never been sampled after preparation of sterile drug products.

OBSERVATION 4

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

Specifically,

A. I observed that non-sterile disinfectant wipes (e.g., (b) (4)) are used to clean the

laminar flow hoods where sterile drug products are prepared.

B. I observed that pharmacy technicians use an expired non-sterile sporicidal agent (e.g., (b) (4)) to clean your classified areas, including the laminar flow hood where sterile drug products are prepared. The bottle stated that the solution expired on 9/17/14.

OBSERVATION 5

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

Specifically, I observed inconsistent and inadequate gowning practices during this inspection as described below:

A. Gowning qualifications have not been conducted for your pharmacy personnel that prepare drug products in your Buffer rooms under the laminar flow hoods.

B. The following non-sterile gowning components are used while preparing sterile drug products:
- Gown
- Facemask
- Hairnet

C. Personnel stated they use (b) gown per day. I observed personnel slide their hands from top to bottom of their gowns, after they hung them on the hooks in the gowning room. In one of the Gowning rooms, I observed that the hanging gowns used during chemotherapy preparations are touching the other hanging gowns that are worn in the Lyophilization Buffer room.

D. There is no demarcation of the dirty and clean side of your Gowning rooms entering into the Buffer rooms. I observed that personnel walked all over the Gowning rooms during their gowning.

E. I observed your cleaning personnel not re-gowning once leaving and re-entering your Buffer rooms, which includes your Chemotherapy Buffer room. In addition, cleaning personnel went from the Chemotherapy Buffer room into your other Buffer rooms without changing his gowning materials.

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OBSERVATION 6

Test procedures relative to appropriate laboratory testing for sterility and pyrogens are not written and followed.

Specifically, your firm has not validated sterility and endotoxin testing to ensure substances in your product formulations do not interfere with these tests.

OBSERVATION 7

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

A. Your firm has never performed testing to determine the preservative (i.e., (b) (4)) content for any of the sterile drug products I reviewed:
   - Super MICCC (Methionine 25 mg, Inositol 50 mg, Choline 50 mg, Chromium 200 mcg, & Cyanocobalamin 700 mcg/ml)
   - Testosterone Cypionate (200 mg/mL)

B. Your firm has never tested the potency or reconstitution time for any of the sterile lyophilized drug products I reviewed:
   - Human Chorionic Gonadotropin (2,000 IU/vial)

OBSERVATION 8

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

A. No documentation (potency and sterility data) could be provided to support your labeled beyond use date for the sterile drug products that I reviewed:

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- 1 year for Human Chorionic Gonadotropin (2,000 IU/vial)
- 5 months for Super MICCC (Methionine 25 mg, Inositol 50 mg, Choline 50 mg, Chromium 200 mcg, & Cyanocobalamin 700 mcg/ml)
- 4 months for Testosterone Cypionate (200 mg/mL)

B. There is no antimicrobial effectiveness testing for sterile drug products that your firm prepares that contain preservatives (e.g., (b) (4)) over the labeled shelf life:
   - Super MICCC (Methionine 25 mg, Inositol 50 mg, Choline 50 mg, Chromium 200 mcg, & Cyanocobalamin 700 mcg/ml)
   - Testosterone Cypionate (200 mg/mL)

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

OBSERVATION 9

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

In addition,

A. I could not verify hold times or the length of time it took to perform critical steps in the preparation of sterile drugs (e.g., Super MICCC, Human Chorionic Gonadotropin, and Testosterone Cypionate), such as (b) (4) or lyophilization of the sterile drug products since batch production and control records were incomplete.

B. No documentation could be provided showing your practice of repackaging 100 mL vials of a drug product (e.g., Super MICCC and Testosterone Cypionate) into 5-10 mL vials at a later date.

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OBSERVATION 10

Each lot of a component, drug product containers, and closures liable to objectionable microbiological contamination is deficiently subjected to microbiological tests before use.

Specifically,

A. Your firm has no qualified vendor program and no documentation could be provided showing you have qualified any of your non-sterile bulk drug substance (e.g., (b) (4) or component suppliers.

B. Your firm has not verified that any Certificate of Analysis (CoA) test results are reliable for any incoming bulk drug substance used in the preparation of sterile drug products.

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