

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 555 Winderley Place, Suite 200 Maitland, FL 32751 (407) 475-4700 Fax: (407) 475-4768	DATE(S) OF INSPECTION 7/13/2017-7/20/2017* FEI NUMBER 3011123993
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Jeffrey S. Steele , CEO and Co-owner
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FIRM NAME Infusion Systems of SW Florida Inc. dba Myerlee Pharmacy	STREET ADDRESS 1826 Boy Scout Dr
CITY, STATE, ZIP CODE, COUNTRY Fort Myers, FL 33907-2113	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written and followed.

THIS IS A REPEAT OBSERVATION

Specifically,

- A. We observed the following aseptic deficiencies during the preparation of sterile drug products:
1. Personnel were observed not sanitizing their gloved hands with (b) (4) prior entering the laminar flow hood (ISO 5) from the buffer room (ISO 7).
 2. Personnel were observed touched her gloved hands and forearm on the surface of the workstation during aseptic processing under the laminar flow hood (ISO 5).
 3. Personnel, wearing a non-sterile bouffant and exposed facial skin, were observed with their head inside the laminar flow hood (ISO 5) for prolonged periods of time.
 4. Personnel were observed cleaning the laminar flow hood (ISO 5) in a non-uniform fashion from the cleanest to dirtiest (i.e. back-to-front) direction.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE June P Page, Investigator Jennifer Lalama, Investigator	June P Page Investigator Signed By: 2000405709 Date Signed: 7/20/2017 X	DATE ISSUED 7/20/2017

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- B. The media fill documented as being conducted by your pharmacist or technicians under the laminar flow hood (ISO 5) in (b) (4) (ISO 7) were found to be deficient for the following reasons:
- Media fills do not simulate current production processes and conditions that represent the most stressful/challenging conditions.
 - For example, on 04/06/2017, performed a media fill of (b) (4) vials using (b) (4) (b) (4), where the worst case scenario is (b) (4) vials ((b) (4)).
 - Prior to June 2016, your firm purchased a (b) (4) (b) (4) that contained a maximum (b) (4) vials. However, this does not represent the most stressful/challenging conditions.
 - Media fills intended to simulate high risk product is (b) (4) during the process, thus sterilizing any potential growth that may have captured by the media fill process.
 - No growth promotion was conducted to ensure the media was suitable to sustain growth.

OBSERVATION 2

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

*** THIS IS A REPEAT OBSERVATION***

Specifically,

- 05/16/2016, a fungus was detected (identified as *Chaetomium spp.*), during your firm's in-house environmental monitoring conducted in ISO 7 area; no corrective measures were documented.
- On 09/23/2016, a fungus was detected (identified as *Alternaria spp.*), during your cleanroom certification report, in your firm's Gowning Room (ISO 7) directly connected to your lab's (b) (4), containing your firm's (b) (4) (ISO5) where high-risk sterile processing occurs; no corrective measures were documented.
- Air (viable and non-viable) sampling within all classified areas is not performed during dynamic conditions during your firm's cleanroom re-certifications or during your in-house environmental

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monitoring.

- D. There is no continuous or at least periodically monitoring of air pressure differentials during production from the (b) (4) room and (b) (4) room to the surrounding non-classified pharmacy area.
1. In addition, your firm's room recertification report (March 2017) documents a differential pressure out-of-limit reading ((b) (4) for the Gowning Room (b) (4) ISO 8 area) when compared to the (b) (4) (ISO 7). No corrective actions were conducted by your firm.
- 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 (b) (4) operations. You firm stated sampling is conducted every (b) (4) .
 2. Your personnel's gowning materials are not routinely sampled after preparation of sterile drug products. On 07/18/2017, your technician stated this was only conducted (b) (4) without documentation.

OBSERVATION 3

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

THIS IS A REPEAT OBSERVATION

Specifically

- A. The (b) (4) (b) (4) sterilization (b) (4) have not been validated. There are no written calibration procedures or calibration documentation available for these pieces of equipment, which would include documentation such as, temperature mapping.
1. The (b) (4) (b) (4) is used for all glassware that comes into direct contact with sterile drug products.
 2. The (b) (4) is used for the (b) (4) stir bars and the rubber vial stoppers on finished

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sterile drug products

- B. The biological indicators used in the verification of your (b) (4) (b) (4) are designed to verify (b) (4). However, your firm's (b) (4) verification logs document your temperatures are set between (b) (4).

OBSERVATION 4

The flow of though the building is not designed to prevent contamination.

Specifically,

- A. On 07/17/2017, we observed your personnel did not sterilize the vial crimper used to secure the plastic flip off seals to the stoppered vial prior to placing it into the laminar flow hood (ISO 5) from the (b) (4) room (ISO 7) during aseptic production of Papaverine/Phentolamine/Alprostadil 30mg/1mg/25mg/ml, lot 07-17-2017@22.
- B. On 07/17/2017, we observed your personnel did not sanitize or cover the (b) (4) with active drug ingredient when being transported from the unclassified area to the (b) (4) room (ISO 7) and again when entering the laminar flow hood (ISO 5) with (b) (4). In addition, the (b) (4) (b) (4) In addition, the non-sterile (b) (4) touch the inside of the sterile syringe.

OBSERVATION 5

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

*** THIS IS A REPEAT OBSERVATION***

Specifically,

- A. Your firm has not determined sterility suitability and endotoxin validation for all of your sterile

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products.

- B. No endotoxin testing was performed on (b) (4) aseptically produced at your firm. These (b) (4) in subsequent drug preparations. For example, on 07/17/2017, your technician used Alprostadil (b) (4) during aseptic production of Papaverine/Phentolamine/Alprostadil 30mg/1mg/25mg/ml, lot 07-17-2017@22. No endotoxin testing was performed on Alprostadil (b) (4)

OBSERVATION 6

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.

*** THIS IS A REPEAT OBSERVATION***

Specifically,

- A. On 06/23/2017, your firm received a sub-potency failure (70.9%) for HCG 5000IU, lot 04-06-2017@17, qty: (b) (4) vials, from your contract laboratory. A prescription dispensing report associated with this lot documents (b) (4) prescriptions (approximately (b) (4) units) were released and dispensed prior to a pharmacist's review.
- B. On 07/06/2017, your firm received a super-potency failure (134%) for HCG 2500IU, lot 06-16-2017@12. However, your firm stated this was a challenge sample where the labeled concentration of HCG was intentionally mislabeled to reflect a lower concentration. Your pharmacist stated the actual concentration of this challenge sample was HCG 5000IU, lot 06-16-2017@12; therefore, this lot was found to be sub-potent (67%). A prescription dispensing report associated with this lot documents (b) (4) prescriptions were released and dispensed prior to a pharmacist's review.
- C. Your firm has never performed potency testing to determine the preservative (i.e., (b) (4) content for any of your firm's sterile drug products.

OBSERVATION 7

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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.

*** THIS IS A REPEAT OBSERVATION***

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:
 - 1. 6 month for Human Chorionic Gonadotropin (2000 IU/vial)
 - 2. 4 months for Testosterone Cypionate (200 mg/mL)
- B. There is no antimicrobial effectiveness testing to ensure efficacy through the beyond use date for all sterile drug products that contain preservatives (e.g., (b) (4)).

OBSERVATION 8

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

THIS IS A REPEAT OBSERVATION

Specifically,

We could not verify hold times or the length of time it took to perform critical steps in the preparation of sterile drugs (e.g., MICCC, Human Chorionic Gonadotropin, and GHRP-6/Sermorelin), such as temperature recordings or lyophilization of the sterile drug products since batch production and control records were incomplete.

OBSERVATION 9

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

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*****THIS IS A REPEAT OBSERVATION*****

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 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.

***DATES OF INSPECTION**

7/13/2017(Thu),7/14/2017(Fri),7/17/2017(Mon),7/18/2017(Tue),7/19/2017(Wed),7/20/2017(Thu)

X
Jennifer Lalama
Investigator
Signed By: Jennifer Lalama -S
Date Signed: 7/20/2017

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Date: September 14, 2017

Jeffrey S. Steele
Infusion Systems of SW Florida Inc. dba Myerlee Pharmacy
1826 Boy Scout Dr
Fort Myers, FL 33907-2113

Subject: System Notification

Dear Jeffrey S. Steele,

We are notifying you that due to a technical error related to a software update, the FDA Form 483 you received recently inadvertently included a sentence meant only for medical device firms. That statement says, "Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements."

This statement refers to quality system requirements applicable only to medical device establishments, but was inadvertently included on certain Form 483's issued to non-device establishments for a brief period of time. Please note that the statement has no bearing on the inspection observations themselves, which remain applicable as of the date that you were issued the Form FDA 483.

Should you have any questions, please send to AskORAIT@fda.hhs.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa Creason", is shown.

Lisa Creason
Director, Office of Information Systems Management
Office of Regulatory Affairs
Food and Drug Administration