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 ORAPHARM2_RESPONSES@fda.hhs.gov	8/2/2022-8/11/2022* FEI NUMBER 3011123993

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jeffrey S. Steele, R.Ph, C.Ph, Owner/Pharmacist

FIRM NAME	STREET ADDRESS
Infusion Systems of SW Florida Inc. dba Myerlee Pharmacy	1826 Boy Scout Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fort Myers, FL 33907-2113	producer of sterile and non-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

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Specifically, on 05/17/2022 your firm had a third party contractor qualify your clean rooms. An objectionable organism was found in the ISO 8 prep room in the viable air sample. The microorganism was identified as Rhizopus. Your firm compounded products before and after the sample collection, including products such as Morphine Sulfate 10mg/mL IV, Vancomycin 25 mg/mL ophthalmic solution, and Papaverine HCl/Phentolamine Triturtate/Alprostadil 30mg/2mg/20ug/mL solution.

OBSERVATION 2

The (b) (4) intended to render final product sterile was not adequate to accomplish sterilization.

Specifically, your firm uses (b) (4) (b) (4) in sterilizing intrathecal products. The (b) (4), (b) (4), are sterilizing (b) (4) and (b) (4) testing is performed. The (b) (4), (b) (4), is used as part of sterility testing and no (b) (4) testing is performed; this (b) (4) is the (b) (4) in contact with the product.

*DATES OF INSPECTION

8/02/2022(Tue), 8/03/2022(Wed), 8/04/2022(Thu), 8/05/2022(Fri), 8/08/2022(Mon), 8/09/2022(Tue), 8/11/2022(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer Lalama, Investigator Steven A Brettler, Investigator	X Steven A Brettler Investigator Signed By: Steven A. Brettler -S Date Signed: 08-11-2022 14:45:43	8/11/2022

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X Jennifer Lalama
Investigator
Signed By: Jennifer Lalama -S
Date Signed: 08-11-2022 14:46:11

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Jennifer Lalama, Investigator
Steven A Brettler, Investigator

X Steven A Brettler
Investigator
Signed By: Steven A. Brettler -S
Date Signed: 08-11-2022
14:45:43

DATE ISSUED
8/11/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."