DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Pharma Division II 404 BNA Drive, Building 200, Suite 500 Nashville, TN 37217 (615) 366-7801 | Email: orapharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	11/18/2019-12/6/2019
	FEI NUMBER 3010704905
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Hunter M. Eaves, PharmD, President	
FIRM NAME Surgery Pharmacy Services, Inc.	STREET ADDRESS 3908 Tennessee Avenue, Suite F
CITY, STATE, ZIP CODE, COUNTRY Chattanooga, TN 37409	TYPE ESTABLISHMENT INSPECTED 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) (WE) OBSERVED:

OBSERVATION 1

Actionable microbial contamination was present in the ISO 5 area or in adjacent areas during aseptic production without adequate product evaluation and remedial action. Specifically, on 5/27/2019, the response to *Bacillus* microbial contamination within ISO 5 Hood (b) (4) did not include testing to determine the extent of impact nor identification and notification of all potentially impacted patients.

OBSERVATION 2

Personnel failed to disinfect or change gloves frequently enough to prevent contamination. Specifically, the technician was observed to disinfect her gloves infrequently during sterile production of TPN products on 11/18/2019. For example, she was observed to move her hands outside of the ISO 5 hood and then back into the hood without sanitization. On 11/19/2019, the technician was observed tying out the trash bag in the large trash bin located in the ISO 7 production room, rolling the bin into the ISO 8 anteroom, and resuming aseptic production activities in the ISO 5 hood after spraying her hands with (b) (4) . She did not change her sterile gloves or sleeves although they had been in contact with the trash bin. On 11/19/2019, she was also observed to spray and wipe down the foldable step-stool, which she uses to reach within the hood during cleaning and production, without changing her sterile gloves before resuming aseptic production activities.

OBSERVATION 3

Personnel engaged in aseptic processing were observed with exposed skin in critical areas. Specifically, on 11/18/2019 and 11/19/2019, the technician was observed with her forehead exposed while leaning significantly into the ISO 5 certified Hood (b) (4) during aseptic production activities.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Samantha J. Bradley	Samantha J. Bradley, Certified Drug Specialist	12/6/2019

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OBSERVATION 4

Equipment, materials, and/or supplies are not disinfected prior to entering aseptic processing areas. Specifically, materials are not adequately disinfected prior to moving them from areas of lower to stricter classifications. Large drug components, such as (b) (4), are "washed" in baskets in a (b) (4) loaded with (b) (4) and then partially dried using a (b) (4) located in the general pharmacy area prior to being placed in the (b) (4) to the ISO 7 production room. Materials are moved into temporary storage baskets within the ISO 7 room without disinfection. When they are used for production, materials are placed on ISO 5 worksurfaces prior to their disinfection within the hoods.

OBSERVATION 5

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. Specifically, the media fills consist of preparing and (b) (4) (b) (4) media into (b) (4) control vials and (b) (4) vials intended to represent finished product, though this is not representative of the worst-case activities such as the manual production and (b) (4) of product in up to (b) (4) syringes intended for intracameral injections.

OBSERVATION 6

Disinfecting agents used in the ISO 5 area are not sterile. Specifically, (b) (4)) is non-sterile and is routinely used for disinfection of the ISO 5 hoods and supporting aseptic processing areas.

OBSERVATION 7

Pressure differentials between areas with different air classifications were not monitored prior or during sterile drug production. Specifically, there is no verification of the pressure differentials before or during sterile drug production. Pressure differentials are measured with (b) (4) manometers which are not visible from within the cleanroom. The values are documented (b) (4); no time is recorded.

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OBSERVATION 8

Your firm released drug product in which the strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. Specifically, the (b) (4) and (b) (4) irrigation solutions have failed assay testing for epinephrine since 02/2019 but they were still produced and dispensed without resolving the failures. Additionally, testing data lacks supporting documentation with the date of production to verify the the assigned 9-day BUD is appropriate for the irrigation solutions.

OBSERVATION 9

The ISO-classified equipment have difficult-to-clean, particle-generating, or visibly dirty equipment or surfaces. Specifically, ISO 5 Hood (b) (4) has a worksurface composed of laminate which is worn and stained on the left side and has been chipped on both front corner edges. This hood is used for sterile drug production and was the only hood in use while Hood (b) (4) was down from about 10/31/2019 through 12/2/2019.

OBSERVATION 10

ISO-5 classified areas were not certified under dynamic conditions. Specifically, unidirectional airflow is not verified under operational conditions representative of the most challenging load and activities. The smoke studies performed only include evaluation of manual manipulations within the hood and do not include evaluation of a fully-loaded hood, such as with the (b) (4) equipment, which takes up a significant amount of space and potentially interrupts the first-pass air due to the (b) (4) airflow hood design.

***DATES OF INSPECTION**

11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/21/2019(Thu), 11/22/2019(Fri), 12/3/2019(Tue), 12/4/2019(Wed), 12/6/2019(Fri)

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