DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
60 Eighth Street NE Atlanta, GA 30309 (404)253-1161 Fax:(404)253-1202 ORAPHARM2_RESPONSES@fda.hhs.gov	6/20/2023-7/7/2023* FEI NUMBER 3010704905

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hunter M. Eaves, Owner/Pharmicist-in-Charge

FIRM NAME	STREET ADDRESS
Surgery Pharmacy Services Inc	3908 Tennessee Ave Ste F
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Chattanooga, TN 37409-1357	Producer of 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.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Smoke studies were inadequately performed under dynamic conditions.

Specifically, your videos of the smoke studies conducted on April 13, 2023 do not show manipulations or conditions performed that would be representative of the dynamic process used in actual compounding processes using the (b) (4) (b) (4) .
For example, the (b) (4) additions of volumes deemed too small to be added to the final products; the connection of the TPN bag to the tubing, the powered on state of the (b) (4) and scale; and connections made to all (b) (4) component stations are not performed during the smoke study.

OBSERVATION 2

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically, your media fills are not representative of production in that manipulations made during production are not reproduced with the media fill process. For example, manipulations not represented are the addition of volumes deemed too small for inclusion via the (b) (4) (b) (4) machine.

OBSERVATION 3

Your facility is designed and operated in a way that may permit the influx of lesser quality air into a higher quality air area.

Specifically, material flows directly from an unclassified area into a ISO 7 classified room in which

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jared P Stevens, Investigator X Jared P Stevens Investigator Signed By Jared P. Stevens -S Date Signed 07-07-2023 11 20 22	7/7/2023

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sterile production occurs via a (b) (4) (b) (4) which consists of (b) (4) with a (b) (4).

On 06/21/2023, materials were used in compounding total parenteral nutrition (TPN) products that included a calibration kit, tubing, and bags which had entered the ISO 7 area via the (b) (4) as well as finished TPN products leaving the ISO 7 area into the unclassified space via this unfiltered (b) (4) This (b) (4) is located within close proximity, approximately three feet, to an ISO 5 hood used in sterile compounding of TPN products.

***DATES OF INSPECTION**

6/20/2023(Tue), 6/21/2023(Wed), 6/22/2023(Thu), 6/23/2023(Fri), 6/26/2023(Mon), 6/29/2023(Thu), 7/05/2023(Wed), 7/07/2023(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jared P Stevens, Investigator X Jared P Stevens Investigator Signed By: Jared P. Stevens -S Date Signed: 07-07-2023 11:20:22	7/7/2023

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."