DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	11/6/2017-11/17/2017* FEI NUMBER 3006372310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stuart H. Burgess, Director of Pharmacy

FIRM NAME	STREET ADDRESS
Intrathecal Compounding Specialist, LLC	206 Jacobs Run
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Scott, LA 70583-8907	Producer of Sterile and Non-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

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

Specifically, employees had positive results multiple times for fingertip testing (which is performed every 2 weeks according to SOP), did not identify the microorganism and continued to produce and distribute sterile drug products.

Tech/RPh	Date	CFUs
(b) (6)	1/16/2017	1
	3/6/2017	1
	4/24/2017	1
	7/10/2017	1
	8/21/2017	1
	9/13/2017	1
	4/20/2017	1
	8/2/2017	1
	1/3/2017	2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Claire M Minden, Investigator	X Claire M Minden Investigator Signed By: Claire M. Minden -S Date Signed: 11-17-2017 07:04:43	11/17/2017

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(b) (6)		
	1/9/2017	2 large, 2 small
	1/16/2017	3
	2/13/2017	1
	2/20/2017	3
	4/17/2017	1 large
	8/30/2017	1
	1/3/2017	1
	1/18/2017	3
	1/25/2017	1 large
	2/8/2017	1
	4/12/2017	1
	4/19/2017	1
	4/26/2017	2 large
	5/3/2017	3
	5/24/2017	1
	7/5/2017	2 large
	7/19/2017	1
	9/6/2017	1
	9/13/2017	1

OBSERVATION 2

You produced highly potent drugs without providing adequate segregation, cleaning of work surfaces and cleaning of personnel to prevent cross-contamination.

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Specifically, during the inspection I observed the following poor aseptic technique in which personnel did not disinfect and change gloves frequently enough to prevent contamination:

- Reaching over items
- Placing a paper label in the laminar flow hood
- Touching the plunger of the syringe
- Multiple products with multiple active ingredients and multiple active pharmaceutical ingredients (bulk solutions) are in the laminar flow hood at the same time with no segregation/separation to prevent mix-ups

OBSERVATION 3

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

OBSERVATION 4

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, during the inspection I observed an employee touch the outside of their gloves with their bare hand, did not disinfect and continued to compound sterile drugs which were further distributed.

OBSERVATION 5

Personnel engaged in aseptic processing were observed with exposed hair and exposed mouth.

Specifically, portions of your face and neck were exposed to the ISO 5 environment during aseptic operations.

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OBSERVATION 6

Personnel engaged in aseptic processing were observed leaving and re-entering the cleanroom from non-classified areas without first replacing gowning apparel.

Specifically, you reuse the same fluid resistant gown throughout the day.

OBSERVATION 7

Equipment was and Materials or supplies were not disinfected prior to entering the aseptic processing areas.

Specifically, supplies, materials and equipment are not decontaminated prior to entering the ISO 5 and ISO 7 environments.

OBSERVATION 8

Non-microbial contamination was observed in your production area.

Specifically, the HEPA filter in the laminar flow hood was observed to be stained brown in areas directly behind the compounding area.

OBSERVATION 9

The ISO 5 classified aseptic processing areas had difficult to clean and particle-generating equipment or surface.

Specifically, I observed threads stuck in the outlet cover in the laminar flow hood which was used throughout this inspection to compound and distribute sterile drugs.

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OBSERVATION 10

Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate levels of disinfection.

Specifically,

- Contact times for each cleaning agent were not followed as observed during this inspection.
- Employees were observed to clean front to back and used the same wipe multiple time.
- Employees were observed to clean during operations using the same portion of one wipe between products one section of the surface of the laminar flow hood.

OBSERVATION 11

ISO-5 classified areas were not certified under dynamic conditions.

Specifically, unidirectional airflow was not verified under operational conditions. Your certification of ISO 5 and ISO 7 areas do not include smoke studies, airflow patterns, HEPA leaking testing and air exchange for the anteroom.

OBSERVATION 12

You have no assurance that the endotoxin level of your intrathecal drug products are safe, since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your bulk solutions (active pharmaceutical ingredients) past the initial compounded date.

OBSERVATION 13

Post filtration integrity testing to the sterilizing filter was not performed.

OBSERVATION 14

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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.

***DATES OF INSPECTION**
11/06/2017(Mon), 11/07/2017(Tue), 11/08/2017(Wed), 11/17/2017(Fri)

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