DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE 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 Industry Information: www.fda.gov/oc/industry	02/6-8 & 14/19
	FEI NUMBER 3006372310

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Kevin M. Schneider

FIRM NAME	STREET ADDRESS
Intrathecal Compounding Specialists, LLC	206A Jacob's Run
CITY, STATE AND ZIP CODE Scott, LA 70583	TYPE OF ESTABLISHMENT INSPECTED Producer of 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 MPLEMENT 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

The ISO classified area underwent a change in air equipment that (b) (4) and you continued to produce and distribute sterile drugs.

Specifically, you replaced the (b) (4) to the sterile suite on February 6, 2019, due to issues with maintaining the coolness of the air ((b) (4) on multiple occasions). Your firm continued to produce and distribute sterile drugs while and after the (b) (4) to the sterile suite was replaced without adequate cleaning and recertification following the installation.

OBSERVATION 2

Inadequate pressure differentials between higher quality air room and lower quality air rooms were observed.

Specifically, you had negative or zero pressure for short periods of time in the buffer room (ISO 7) and anteroom (ISO 8) on January 2, 2019. Additionally, there were multiple times on twenty-one days when the pressure was lost in the (b) (4) room from November 28, 2018 to December 28, 2018. You have no pressure data for January 24, 2019 to February 7, 2019 between the anteroom and (b) (4) oom as well as when the (b) (4) was being changed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Claire M. Minden Digitally signed by Claire M. Minden -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13001781022, cn=Claire M. Minden -S Date: 2019.02.14 08:52:20 -06'00'	Claire M. Minden, Investigator	02/14/2019

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OBSERVATION 3
The use of sporicidal agents in the cleanrooms and ISO 5 area is inadequate or infrequent.

Specifically, you do not use a sporicidal cleaner at a minimum monthly.

OBSERVATION 4
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worse-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your media fills include (b) (4) with minimal manipulations and do not include syringes at all or the number of syringes produced for stock solutions.

OBSERVATION 5
Personnel donned gowning apparel improperly, that may have caused the gowning apparel to become contaminated.

Specifically, you don non-sterile face masks in an uncontrolled environment which do not cover your entire face and lean into the ISO 5 hoods during aseptic operations.

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