DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	10/2/2017-12/18/2017*
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nasim P. Barrack, Chief Consultant Pharmacist and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Innovative Intrathecal Solutions, Inc. dba Innovative Compounding Pharmacy	41538 Eastman Dr, Suite A
CITY, STATE, ZIP CODE, COUNTRY Murrieta, CA 92562-8007	TYPE ESTABLISHMENT INSPECTED Producer of Human and Veterinary 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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, your firm's media fill studies are used to support all sterile produced drug products. The media fill studies performed on 1/7/2017 and 6/30/2017 by all three pharmacists who handle the sterile drug product preparations (b) (6), (b) (6), and (b) (6), were deficient in that:

A. The media lots used in the studies were not demonstrated to support the microbial growth through growth promotion test.
B. There were no control samples documented in the media fill reports. The use of control samples is required by your firm's media fill procedure.
C. There were no records showing the quantities of media used in the media fill studies.
D. There were no records of (b) (4) used in the media fill studies.
E. There were no records indicating that the (b) (4) was evaluated.
F. No environmental and personnel monitoring were carried out at the time media fill studies were performed on 6/30/2017.
G. The incubator used for the media samples was not qualified.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Liming Zhang, Investigator Alan P Kurtzberg, Generic Drug User Fee Amendments (GDUFA)	X Liming Zhang Investigator Signed By: 2001400144 Date Signed: 12-18-2017 09:40:36	12/18/2017

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Specifically,

A. Your firm's (b) (4) after each lot of sterile drug product preparation is not adequate in that the test result is subjectively assessed by your pharmacist (b) (4) the (b) (4) through (b) (4) during (b) (4) to evaluate the (b) (4) of the (b) (4) rather than a quantitative measurement. There is no specification for this assessment.

B. On 12/5/2017 during the preparation of Methylcobalamin Injection lot 12052017@16 by pharmacist (b) (6) a non-sterile wipe was observed to be used inside the ISO 5 LFH to clean the ISO 5 bench, walls, and the exterior of container closures including the vial stopper surface that was punctured to introduce sterile drug product into the vial.

Per your PIC's estimate, your firm prepares on average about (b) (4) sterile drug product units a day.

OBSERVATION 3

Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically, the following gowning materials used during the preparation of sterile drug products are not of sterile grade: hair bonnet, mask, lab coat, and shoe cover. In the past 3 months (b) (4) lots of the sterile Omnipaque Injection office stock were produced.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not perform environmental monitoring when sterile drug products are prepared. In addition, personnel monitoring is not carried out after sterile drug preparations. In the past 3 months, (b) (4) lots of the sterile Omnipaque Injection office stock were produced.

OBSERVATION 5

Results of stability testing are not used in determining appropriate storage conditions and expiration dates.

Specifically, the 180 days of beyond use date (BUD) for the Omnipaque Injection product prepared by your firm was not supported by stability data.

OBSERVATION 6

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Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically, not all batches of sterile drug products prepared by your firm were tested for sterility and/or endotoxin before release. For example,

Your firm prepared Omnipaque Injection sterile drug product for doctor office stock by using commercially purchased sterile product to repackage it to smaller volume through (b)(4) However, no sterility and/or endotoxin tests were performed on each batch before release. For example,

A. Omnipaque 300 mg/mL Injection product lot 10042017@44 ((b)(4) units of 10 mL vial distributed) and lot 11282017@34 ((b)(4) units of 3 mL vial distributed) were not tested for sterility and endotoxin.
B. Omnipaque 300 mg/mL Injection product lot 10132017@4 ((b)(4) units of 6 mL vial distributed) and lot 11032017@40 ((b)(4) units of 10 mL vial distributed) were only tested for sterility, but not endotoxin.

***DATES OF INSPECTION**
10/02/2017(Mon), 12/04/2017(Mon), 12/05/2017(Tue), 12/06/2017(Wed), 12/07/2017(Thu), 12/08/2017(Fri), 12/18/2017(Mon)

X Alan P Kurtzberg
Generic Drug User Fee Amendments (GDUFA)
Signed By: Alan P. Kurtzberg -S
Date Signed: 12-18-2017 09:41:47

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	Liming Zhang, Investigator Alan P Kurtzberg, Generic Drug User Fee Amendments (GDUFA)	X Liming Zhang Investigator Signed By: 2001400144 Date Signed: 12-18-2017 09:40:26	12/18/2017