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	10/19/2021-10/26/2021*
	FEI NUMBER 3013556857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Nasim P. Barrack, Chief Consultant Pharmacist and Partial Owner

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

OBSERVATION 1

You produced hazardous drugs without providing adequate containment, segregation and cleaning of personnel to prevent cross-contamination.

Specifically,

On 12-Oct-2021, during the cleaning process before and after compounding of hazardous non-sterile drug product (Progesterone Phytobase, Lot 10192021), we observed that the technician's personal protective equipment (PPE), particularly the sleeve of the gown, was constantly in direct contact and rubbing on the surface of the work bench located in the NIOSH hazard compounding room. Since the same PPE gown is used throughout the day and the firm may compound different types of hazardous drug products, there is a risk of potential carryover of one hazardous non-sterile drug product to the next drug product. Furthermore, procedure 05-A-11A.01, "Competency Assessment: Hazardous Drug Hand Hygiene and Garbing", Date 3/20, does not require gowning or sleeves be changed between the compounding of different drug products.

***DATES OF INSPECTION**

10/19/2021(Tue), 10/20/2021(Wed), 10/21/2021(Thu), 10/22/2021(Fri), 10/25/2021(Mon), 10/26/2021(Tue)

Truong X Nguyen
Consumer Safety Officer
Signed By: Truong X. Nguyen -S
Date Signed: 10-26-2021 12:07:39
X

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott N Lim, Consumer Safety Officer Truong X Nguyen, Consumer Safety Officer Scott N Lim Consumer Safety Officer Signed By: 2002619245 Date Signed: 10-26-2021 12:06:44 X	10/26/2021

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."