DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214)253-5200 Fax:(214)253-5314	8/18/2015-9/1/2015* FEI NUMBER 3004107906

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dr. Mary P. Moyer , President & Chief Science Officer

FIRM NAME	STREET ADDRESS
INCELL Corporation LLC	12734 Cimarron Path
CITY, STATE, ZIP CODE, COUNTRY San Antonio, TX 78249-3424	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

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

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

Specifically, pressure gauges are not installed to monitor the pressure differential or air flow between the ISO 7 Cleanroom, the ISO 8 ante room and the unclassified general environment. The ISO 7 Cleanroom - is where the (b) (4), Serial Number: (b) (4), Equipment ID: (b) (4)) is located. The ISO 5 zone is within the (b) (4) where production of the (b) (4) (b) (4) is conducted. The ISO 8 ante-room is located adjacent to the ISO 7 clean room and the donning of Personal Protective Equipment (PPE) is performed in this area. The following two batches of (b) (4) were produced and distributed without the monitoring of pressure differentials.

Lot #	Date Produced	# of vials produced	Expiration Date	Date Shipped
(b) (4) (b) (4)	6/8/2015	(b) (4)	(b) (4)	6/15/2015
(b) (4) (b) (4)	7/1/15	(b) (4)	(b) (4)	7/15/15 (b) (4) (b) (4) 8/11/15 (b) (4) (b) (4)

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EMPLOYEE(S) SIGNATURE
Patrice S Hall, Investigator
Patrice S Hall

X Patrice S Hall
Patrice S Hall
Investigator
Signed by: Patrice Hall -5

DATE ISSUED
9/1/2015

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OBSERVATION 2

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

Specifically,

1. Your firm does not perform (b) (4) on any of the sterile (b) (4) (b) (4) (b) (4) The following two batches of (b) (4) were processed and distributed with the (b) (4) (b) (4) and were not (b) (4)

Lot #	Date Processed with (b) (4) (b) (4)	# of vials produced	Expiration Date	Date Shipped
(b) (4) (b) (4)	6/8/2015	(b) (4)	(b) (4)	6/15/2015
(b) (4) (b) (4)	7/1/15	(b) (4)	(b) (4)	7/15/15 (b) (4) 8/11/15 (b) (4)

2. Media Fills are not performed by your firm of the operators that process (b) (4) (b) (4) products. There is no written procedure that closely simulates actual production conditions or cover worst case or most challenging conditions. Routine production of the two batches of (b) (4) processed, the firm fills (b) (4)

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	Patrice S Hall, Investigator PSH 9/1/2015 X Patrice S Hall Patrice S Hall Investigator Signed by: Patrice Hall -S	9/1/2015

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(b) (4)

Additionally, the smoke study conducted by a contracted testing laboratory on (b) (4) for the (b) (4), ISO 5 zone was not performed during dynamic conditions.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically, your firm uses non-sterile disinfectants to disinfect the ISO 7 clean room where processing is performed. The non-sterile disinfectants used to clean the walls and floors (b) (4) are: (b) (4), (b) (4), and (b) (4). The following two batches of (b) (4) (b) (4) were produced in the ISO 7 Cleanroom- where non-sterile disinfectants were used and distributed to your customer.

Lot #	Date Produced	# of vials produced	Expiration Date	Date Shipped
(b) (4) (b) (4)	6/8/2015	(b) (4)	JUN 2017	6/15/2015
(b) (4) (b) (4)	7/1/15	(b) (4)	JUL 2017	7/15/15 (b) (4) (b) (4) 8/11/15 (b) (4)

Additionally, the firm utilizes (b) (4), which is (b) (4) (b) (4) (b) (4)) sterilized by the firm, to disinfect the ISO 5 zone inside the (b) (4) where processing is performed.

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OBSERVATION 4

The container labels of your outsourcing facility?s drug products are deficient.

Specifically,
The following information is not found on your (b) (4) product label:
1. The statement, "Office Use Only"
2. The inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

***DATES OF INSPECTION**

8/18/2015(Tue),8/19/2015(Wed),8/20/2015(Thu),9/01/2015(Tue)

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	Patrice S Hall, Investigator PSH Patrice Hall	9/1/2015 X Patrice S Hall Patrice S Hall Investigator Signed by: Patrice Hall-S	9/1/2015