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	3/5/2019-3/12/2019* FEI NUMBER 3011624368

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kimberly I. Young, Director of Operations

FIRM NAME	STREET ADDRESS
Option Care Enterprises, Inc. dba Option Care	9601 Baptist Health Dr., Ste 330
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Little Rock, AR 72205-6325	Producer of 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

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

Specifically, on 03/05/19, I observed two operators place (b) (4) in ISO 5 hoods (b) (4) and (b) (4) without wiping with (b) (4) sterile (b) (4) during the production of Milrinone 60mg, Rx (b) (6) and TPN 3:1, Rx (b) (6) respectively.

OBSERVATION 2

Your facility design allowed the influx of poor quality air into a higher classified area.

Specifically, on 03/05/19, I observed the door from the non-classified area to the ISO 7 ante room open at the same time the door from the ISO 7 ante room to the ISO 7 (b) (4). This occurred during the production of Vancomycin HCL, Rx (b) (6) Milrinone 60mg, Rx (b) (6) and TPN 3:1, Rx (b) (6)

OBSERVATION 3

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.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jennifer L Huntington, Investigator	X Jennifer L. Huntington Investigator Signed By: Jennifer L. Huntington -S Date Signed: 03-12-2019 09:11:50	3/12/2019

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Specifically, media fills are not representative of the maximum batch size for aseptic operations for syringes and IV bags. For example, your firm produced (b) (4) syringes of (b) (4) Rx (b) (6) on 12/12/18, however your media fill consists of (b) (4) vials, (b) (4) syringes, and (b) (4) IV bag.

***DATES OF INSPECTION**
3/05/2019(Tue), 3/06/2019(Wed), 3/07/2019(Thu), 3/08/2019(Fri), 3/12/2019(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jennifer L Huntington, Investigator X Jennifer L. Huntington Investigator Signed By: Jennifer L. Huntington -S Date Signed: 03-12-2019 09:11:50	3/12/2019