DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	DATE(S) OF INSPECTION 9/1/2016-9/21/2016* FEI NUMBER 3012188090
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Kenneth J. Kollmann, RPh , Area Vice President of Operations Great Lakes	
FIRM NAME Option Care	STREET ADDRESS 1226 N Michael Dr Ste A
CITY, STATE, ZIP CODE, COUNTRY Wood Dale, IL 60191-1056	TYPE ESTABLISHMENT INSPECTED 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

A finished drug product has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

Specifically, appropriate controls to prevent the contamination of sterile drug products produced at your facility are not in place.

- Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

  Gowning worn by employees performing aseptic operations including eyewear (if applicable), hair bonnets, beard covers (if applicable), face masks, and lab coats/coveralls are stored and donned inside the ante room where the hand sink is located. Per your firm's policy, (b) (4) [redacted].

- Personnel were observed to be moving rapidly in the vicinity of open sterile units or instruments, which disrupted the airflow and increased the risk of bringing lesser quality air into the ISO 5 area.

  Employees were observed on 9/1/2016 (b) (4) [redacted] drug products in the ISO 5 LAF hoods while other in-process components awaiting aseptic production were staged inside. According to S.K., National Manager of Pharmacy Operations, the (b) (4) [redacted] of some

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Christopher D Leach, Investigator	9/21/2016 X Christopher D Leach Christopher D Leach Investigator Signed by: Christopher D. Leach -S	DATE ISSUED 9/21/2016

drug products (b) (4) [redacted]

- Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.

  Wipes used in the ISO 5 area are not stored in a manner which maintains sterility prior to use. ISO 5-certified LAF hoods and (b) (4) hoods are cleaned according to procedure number P-130, Cleaning and Disinfecting of Compounding Area, revision dated 5/17/2016. (b) (4) [redacted] (b) (4) [redacted]. However, these low particle shedding wipes are removed from their primary packaging and stored in the ISO 7 clean room areas for an undetermined length of time inside open-top, red plastic bins above the LAF hoods or on a shelf below the work surface.

- Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

  Employees observed on 9/1/2016 using either (b) (4) wipes or spray bottles of sterile (b) (4) (b) (4) [redacted] did not consistently ensure that the portion of the drug vial, container, or (b) (4) packaging being held by a gloved hand and therefore shielded from contact was disinfected before moving it into the ISO 5 LAF hoods.

***DATES OF INSPECTION**
9/01/2016(Thu),9/02/2016(Fri),9/07/2016(Wed),9/08/2016(Thu),9/13/2016(Tue),9/15/2016(Thu),9/21/2016(Wed)