DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	5/8/2017-5/18/2017* FEI NUMBER 3009486960

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary K. Moe , Sr Director of Operations

FIRM NAME	STREET ADDRESS
Option Care Enterprises, Inc.	728 134th St SW , Suite 128
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Everett, WA 98204	Producer of sterile 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 I OBSERVED:

OBSERVATION 1

Disinfecting agents used in the ISO 5 area are not sterile. Specifically,

A non-sterile germicidal detergent is used (b) (4) in the cleaning of the ISO 5 "PECs" (primary engineering controls) as well as all work surfaces in the ISO 7 (b) (4) ISO 7 (b) (4) and ISO 7 (b) (4) . The germicidal detergent is rotated (b) (4) . Non-sterile (b) (4) is used in (b) (4) ; non-sterile (b) (4) is used in (b) (4)

OBSERVATION 2

A non-sterile tool was used in the production of drugs. Specifically,

On 5/9/17 a reusable (b) (4) device was observed used in the production of Rx (b)(6),(b)(7)(C) TPN 3 in 1 in the ISO 5 (b) (4) laminar flow hood (LFH) # (b) (4) (b) (4) . Apparent black particles were observed between the (b) (4) of the reusable (b) (4) device.

OBSERVATION 3

Apparent rust/discoloration was observed in the ISO 5 area. Specifically,

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tracy K Li, Investigator 5/19/2017 X Tracy K Li Tracy K Li Investigator Signed by: Tracy K. Li -S	5/19/2017

Apparent rust/discoloration was observed on the (b) (4) vial rack holding Sodium Chloride 4mEq/mL in the ISO 5 (b) (4) LFH # (b) (4) (b) (4)

OBSERVATION 4

Placement and/or use of non-sterile material within the ISO 5 area. Specifically,

A) Opened non-sealing packages of sterile (b) (4) was observed used in the cleaning of ISO 5 (b) (4) LFHs. The (b) (4) were also observed used in disinfecting of drug components prior to use in the ISO 5 (b) (4) LFHs.

B) Non-sterile (b) (4) is used to cover the work surfaces of ISO 5 (b) (4) for the production of hazardous drugs.

C) On 5/8/17, 5/9/17, 5/10/17, and 5/12/17 the sleeves of the non-sterile gowns worn by Technicians were observed touching the work benches within the ISO 5 (b) (4) LFHs during sterile drug production.

OBSERVATION 5

There is no cleaning of the dust-collecting areas in the area surrounding the ISO 5 area. For example:

Apparent dust and black particles were observed on the ISO 7 surface directly underneath the fluorescent lights for ISO 5 (b) (4) LFH # (b) (4) (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	5/8/2017-5/18/2017*
	FEI NUMBER 3009486960

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary K. Moe , Sr Director of Operations

FIRM NAME	STREET ADDRESS
Option Care Enterprises, Inc.	728 134th St SW , Suite 128
CITY, STATE, ZIP CODE, COUNTRY Everett, WA 98204	TYPE ESTABLISHMENT INSPECTED Producer of sterile drug products

OBSERVATION 6

ISO-5 classified areas were not certified under dynamic conditions. Uni-directional airflow was not verified under operational conditions. Specifically,

The smoke studies performed on 5/5/16 and 11/2/16 on the ISO 5 (b) (4) LFH # (b) (4) (b) (4), serial no. (b) (4); (b) (4) LFH # (b) (4) (b) (4); (b) (4) LFH # (b) (4); serial no. (b) (4) were not conducted under dynamic conditions. For example:

A) The smoke study conducted on 5/5/16 was not conducted under operational conditions as evident by your smoke study video which shows the absence of production equipment, drug components, containers and closures in each of the LFHs. A mock sterile-to-sterile transfer from a drug vial to a syringe was performed in each LFH.

B) On 11/2/16 you performed a mock sterile-to-sterile transfer from a drug vial to a syringe in the ISO 5 LFH # (b) (4) which houses the production equipment (b) (4). You did not perform a mock fill using the (b) (4) used for the production of total ~~parental~~ **parenteral** nutrition drugs.

OBSERVATION 7

Your media plates for environmental monitoring and personnel monitoring were not incubated appropriately to ensure your production process and production facility do not have insanitary conditions and that they are suitable for sterile drug production Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tracy K Li, Investigator 5/19/2017 X Tracy K Li Tracy K Li Investigator Signed by: Tracy K. Li -S	5/19/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	5/8/2017-5/18/2017*
	FEI NUMBER 3009486960

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mary K. Moe , Sr Director of Operations

FIRM NAME	STREET ADDRESS
Option Care Enterprises, Inc.	728 134th St SW , Suite 128
CITY, STATE, ZIP CODE, COUNTRY Everett, WA 98204	TYPE ESTABLISHMENT INSPECTED Producer of sterile drug products

Your incubator temperature logs from your electronic monitoring system (b) (4) shows the incubator was operating between temperatures of (b) (4)° F; however this temperature range is below the manufacturer (b) (4) for Environmental Monitoring instruction for incubation which states, "[i]ncubate exposed plates at (b) (4)° C [(b) (4) °F] for (b) (4)n***". These environmental samples and personnel samples were:

~~A) SOP P164 Personnel Training and Evaluation in Aseptic Manipulation Skills; revised 4/15/17 describes "medium and low risk" media fill runs where "media-fill units are incubated at~~ (b) (4) ~~(b) (4) °C for (b) (4) days. After (b) (4) days, the units are incubated at (b) (4)° Celsius [(b) (4) ° F] for an additiona (b) (4) days." Your records indicate (b) (4) employees performed "medium and low risk" media fills on 8/11/16, 8/16/17, 9/27/16, 10/28/16, and 1/6/17; these media-filled units were incubated under the temperature of (b) (4)° F which is not the established specification.~~

B**A**) ~~SOP P-165 Environmental Monitoring; revised 3/14/16 describes incubation of media plates for viable air and surface samples for (b) (4) hours at (b) (4)° Celsius ((b) (4) ° F), followed by storage for (b) (4) additional days at (b) (4) °C).~~ Viable air samples were collected on (b) (4) (b) (4) . Surface samples were collected on (b) (4) These viable air and surface samples were incubated under the temperature of (b) (4)° F which is not the established specification.

C**B**) ~~SOP P164 Personnel Training and Evaluation in Aseptic Manipulation Skills; revised 4/15/17 describes the monitoring of media plates for gloved fingertip sampling as "(b) (4)° Celsius [(b) (4) ° F] for (b) (4) hours followed by monitoring at (b) (4) °C) for (b) (4) additional days." (b) (4)~~ employees performed gloved fingertip sampling on (b) (4) , (b) (4) ; these samples were incubated under the temperature of (b) (4)° F which is not the established specification.

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tracy K Li, Investigator	5/19/2017 X Tracy K Li Tracy K Li Investigator Signed by: Tracy K. Li -S	DATE ISSUED 5/19/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	5/8/2017-5/18/2017*
	FEI NUMBER 3009486960

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mary K. Moe , Sr Director of Operations

FIRM NAME	STREET ADDRESS
Option Care Enterprises, Inc.	728 134th St SW , Suite 128
CITY, STATE, ZIP CODE, COUNTRY Everett, WA 98204	TYPE ESTABLISHMENT INSPECTED Producer of sterile drug products

OBSERVATION 8

There is no record for monitoring of pressure differentials between adjacent rooms in the Compounding Area and no record for cleaning when drugs were produced on the weekends. These drug productions were:

A) Drug produced on 2/12/17: Rx (b)(6),(b)(7)(C) Cefepime 2 g/20 mL SW syringe (IV push).

B) Drugs produced on 3/26/17: Rx (b)(6),(b)(7)(C) Vancomycin 1 g/100 mL NS eclipse; Rx (b)(6),(b)(7)(C) Vancomycin 1.5 g/250 mL NS eclipse.

C) Drug produced on 4/16/17: Rx (b)(6),(b)(7)(C) Ertapenem 1 g/100 mL NS Mini-Bag Plus (Invanz)

***DATES OF INSPECTION**
5/08/2017(Mon),5/09/2017(Tue),5/10/2017(Wed),5/12/2017(Fri),5/18/2017(Thu)

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Tracy K Li, Investigator	5/19/2017 X Tracy K Li Tracy K Li Investigator Signed by: Tracy K. Li -S	DATE ISSUED 5/19/2017