

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

**DISTRICT OFFICE ADDRESS AND PHONE NUMBER**

22215 26th Ave SE Suite 210  
Bothell, WA 98021  
P: 425-302-0340  
F: 425-302-0404

**DATE(S) OF INSPECTION**

02/09/16, 02/10/16, 02/11/16, 02/17/16,  
2/18/16, 2/25/16

**FEI NUMBER**

3009486960

Industry Information: [www.fda.gov/oc/industry](http://www.fda.gov/oc/industry)

**NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED**

**TO:** Maritza D. DeGagne, RPh, Area Vice President, NW

**FIRM NAME**

Option Care Enterprises, Inc.

**STREET ADDRESS**

8120 Evergreen Way

**CITY, STATE AND ZIP CODE**

Everett, WA 98203

**TYPE OF ESTABLISHMENT INSPECTED**

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) (WE) OBSERVED:

**OBSERVATION 1**

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

Specifically,

A) Your firm does not investigate the impact of positive environmental microbiological results on sterile injectable drug products. SOP P-165 "Environmental Monitoring" Revised date 12/04/2015, section Action Steps For Positives Samples, states in part: "\*\*\*\*If the results of the microbial identification (b) (4) (b) (4)

microorganisms include gram-negative rods, coagulases positive staphylococcus, molds, and yeasts\*\*\*\*". For example, there was no investigation performed after the following gram-negative rods were identified in the ISO 5 and ISO 8 areas:

- 1) On June 16, 2015 after surface sampling of the (b) (4) (b) (4) one gram negative rod was identified as Acinetobacter baumannii.
- 2) On Dec 15, 2015 after air sampling (b) (4), one gram negative rod was identified as Brevundimonas intermedia.

B) Your environmental monitoring procedure SOP P-165 "Environmental Monitoring" Revised date 12/04/2015 is deficient in that there is no scientific rationale to support the frequency of testing:

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**EMPLOYEE(S) SIGNATURE**

*Sangeeta M. Khurana*  
*Gerard P. DeLeon*

**EMPLOYEE(S) NAME AND TITLE (Print or Type)**

*Harijo B. Kambore, Investigator*  
SANGEETA M. KHURANA, Investigator  
Gerard P. DeLeon, Investigator

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1) Surface sampling for microbiological monitoring is not performed each day in the ISO 5 hoods when sterile drugs are produced. Instead surface sampling is performed (b) (4). The most recent (b) (4) active surface samplings were conducted on (b) (4).

2) Active air sampling for microbiological monitoring is not performed each day in the ISO 5 hoods when sterile drugs are produced. Instead viable monitoring using an air sampler is performed (b) (4). The most recent (b) (4) air samplings were conducted on (b) (4).

3) Personnel monitoring of operators is not performed each day that a batch of sterile drug is produced. Instead personnel monitoring is performed (b) (4). In addition, personnel monitoring (b) (4). The firm last performed monitoring of Technicians (b) (6), (b) (7)(C) on (b) (4), (b) (6), (b) (7)(C) on (b) (4), (b) (6), (b) (7)(C) on (b) (4).

C) During our review of in situ air pattern analysis (smoke studies) completed on (b) (4) we found that the smoke studies (b) (4) were not conducted under dynamic conditions, simulating routine filling activities. For example on February 9, 2016 during the filling of sterile injectable drug products we observed (b) (4) operators working in the ISO 7 clean room. (b) (4) operator was making Total Parenteral Nutrition (TPN), (b) (4), Batch # (b) (6), (b) (7)(C), Expiration Date 02/18/2016 using the ISO 5 hoods (b) (4). (b) (4) operator was making Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C), Expiration Date 02/16/2016 in the ISO 5 hood (b) (4). The smoke studies conducted on (b) (4) were deficient in that:

- 1) No operators were working in any of the ISO 5 hoods;
- 2) Not all interventions were introduced during the smoke studies such as set-up for filling operations or multiple activities conducted during the filling by the operators;
- 3) There is no documentation to support that the smoke studies were reviewed by the firm personnel and if the smoke studies were adequate.

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FIRM NAME Option Care Enterprises, Inc.	STREET ADDRESS 8120 Evergreen Way	
CITY, STATE AND ZIP CODE Everett, WA 98203	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile Drug Products	

**OBSERVATION 2**

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

Specifically,

A) On February 9, 2016 the following inadequate aseptic techniques were observed:

1) Technician (b) (6), (b) (7)(C) was observed touching non-sterile items such as the inner liner of a waste receptacle and a metal cart. Technician (b) (6), (b) (7)(C) then moved in and out of the ISO 5 hood without always sanitizing or changing her gloves while handling components used in the filling of Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C)

2) Operators were observed working deep inside the ISO 5 hoods with parts of their non-sterile garbing materials exposed inside the ISO 5 hoods. For example,

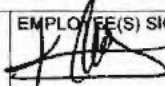
i. Technician (b) (6), (b) (7)(C) was observed (b) (4) for the preparation of TPN (b) (4), Batch # (b) (6), (b) (7)(C) with the sleeve of her non-sterile lab coat exposed under the ISO 5 hood (b) (4)

ii. Technician (b) (6), (b) (7)(C) was observed manipulating components for the preparation of Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C) with the sleeves of her non-sterile lab coat exposed under the ISO 5 hood (b) (4)  
(b) (4)

3) During the filling of the above (b) (4) Total Parenteral Nutrition bags, we observed Technician (b) (6), (b) (7)(C) going in and out of the ISO 5 hood moving rapidly to grab and replace the component bags to keep filling the (b) (4) Total Parenteral Nutrition bags potentially disrupting the unidirectional airflow.

4) The door separating the ISO 7 clean room and the ISO 8 anteroom is made of wooden materials and is not easily cleanable.

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B) The media fill program is deficient in that the media fill procedure uses a "(b) (4)" and does not simulate the actual and/or worst case filling operations such as producing TPN's.

**OBSERVATION 3**

Clothing of personnel engaged in the manufacturing and processing of drug products is not appropriate for the duties they perform.

Specifically, the attire worn by operators on February 9, 2016 during the filling of sterile injectable drugs TPN (b) (4), Batch # (b)(6),(b)(7)(C) and Ertapenem 1g/100mL NS Eclipse, Batch # (b)(6),(b)(7)(C) was inadequate as follows:

A) (b) (4) Technicians were observed working in the ISO 5 hoods (b) (4) wearing disposable non-sterile head covers, non-sterile surgical masks, non-sterile lab coat, and non-sterile shoe covers.

B) The non-sterile surgical masks and non-sterile head covers worn by the (b) (4) technicians did not provide adequate coverage to the forehead, neck, or face. The Technicians were also not wearing protective eyewear.

C) The firm SOP P-128 "Proper Attire, Garbing and Hand Washing for Clean Room Personnel", Revised date 10/26/2015, states in part: "\*\*\*\*Clean room attire that includes scrubs and shoes (b) (4) was not followed. Technician (b)(6),(b)(7)(C) confirmed that the operators are allowed (b) (4)

Upon returning to the ISO 7 clean room and resuming filling activities in the ISO 5 hoods the operators (b) (4).

D) The firm SOP P-128 section "Company Issued Clean Room Attire" paragraph six states in part:

(b) (4) \*\*\*\*. Technician (b)(6),(b)(7)(C) confirmed that the firm's issued non-sterile scrubs are (b) (4).

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- 1) There are no detailed instructions in SOP P-128 on the frequency of cleaning the non-sterile scrubs.
- 2) There are no instructions in SOP P-128 on how to protect the non-sterile scrubs from potential contamination during operator movement from unclassified areas to the ISO 7 clean room where sterile injectable drugs are produced in the ISO 5 hoods.

**OBSERVATION 4**

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

Specifically,

A) Non-sterile (b) (4) are used to clean the ISO 5 hoods and ISO 7 clean room. On February 9, 2016, Technician (b) (6), (b) (7)(C) was observed spraying the inside surface of the ISO 5 (b) (4) with sterile (b) (4) and then wiping the surface with non-sterile (b) (4) prior to and during the filling of Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C)

B) On February 9, 2016, apparent staining were observed on the metal grates covering the HEPA filter of the ISO 5 hoods (b) (4) during the filling of TPN (b) (4), Batch # (b) (6), (b) (7)(C). Also, apparent staining were observed on the metal grates covering the pre-filters of the ISO 5 hood (b) (4) during the filling of Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C).

**OBSERVATION 5**

The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically, on February 9, 2016, the operators failed to follow your sterile compounding and aseptic technique procedures during the filling of sterile injectable drugs TPN (b) (4) Batch # (b) (6), (b) (7)(C) and Ertapenem 1g/100mL NS Eclipse, Batch # (b) (6), (b) (7)(C) as follows:

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A) We observed a (b) (4) that is located between ISO 5 hoods (b) (4) (b) (4) in the ISO 7 clean room. The (b) (4) SOP P-125, "Sterile Compounding Environment Procedures" states in part: "\*\*\*\* (b) (4)

B) During (b) (4) were not protected from potential lint shedding. SOP P-132, "Aseptic Technique Procedures" states in part: (b) (4)

**OBSERVATION 6**

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, sterility testing is not performed on each batch, or representative batches of filled sterile injectable drug products. For example, no sterility testing is performed on batches of sterile-to-sterile filled, preservative free, drug products such as: (1) Ertapenem 1gm/100 mL (BUD 7 days at refrigerated condition); (2) Total Parenteral Nutrition, (b) (4) (BUD 9 days at refrigerated condition); (3) Ceftriaxone 2 gm/20 mL (BUD 9 days at refrigerated condition); and (4) Cefazolin 2 gm/20 mL (BUD 9 days at refrigerated condition).

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**OBSERVATION 7**

The drug product is not identified with a lot or control number that permits the determination of the history of the manufacture and control of the batch.

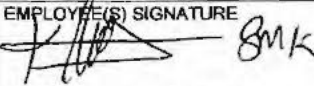
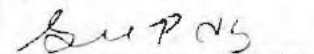
Specifically, the firm does not have a procedure describing the storage and reuse of (b) (4). The (b) (4)

The prescription number and the number of units of (b) (4) are not always documented to ensure adequate traceability of individual units. On February 9, 2016, we observed the following sterile injectable drug products stored in a bin labeled as (b) (4) in a refrigerator located in the ISO 8 anteroom:

**(b) (4) MEDS OBSERVED IN THE ISO 8 ROOM REFRIGERATOR**

PRODUCT	QUANTITY	FILLED DATE	EXPIRATION DATE	BEYOND USE DATE
Cefazolin 2 gm/20 mL	(b) (4) X 20 mL syringes	2/1/2016	2/10/2016	9 days
Cefazolin 2 gm/20 mL	(b) (4) X 20 mL syringes	2/2/2016	2/11/2016	9 days
Vancomycin 1.75 gm/400 mL	(b) (4) X 400 mL units	2/2/2016	2/11/2016	9 days
NS Eclipse				
Buffered Lidocaine 1% 10 mg/mL	(b) (4) X 22.2 mL vial	2/4/2016	2/11/2016	7 days
Ertapenem 1 gm/100 mL NS Eclipse	(b) (4) X 100 mL unit	2/8/2016	2/15/2016	7 days
Ceftriaxone 2 gm/20 mL	(b) (4) X 20 mL syringes	2/8/2016	2/17/2016	9 days

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	 <b>SMK</b>	<b>Sungeeta Mund Khurana, Investigator</b>	