

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 5/15/2017-6/1/2017* FEI NUMBER 3008231170
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Estee Altman (aka Esther Altman) , CEO
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FIRM NAME Infusion Options, Inc.	STREET ADDRESS 5924 13th Ave
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CITY, STATE, ZIP CODE, COUNTRY Brooklyn, NY 11219-4934	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Outsourcing Facility
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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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include validation of the sterilization process.

Specifically:

Media fills (aseptic process simulations) are not representative of routine production in that the number of units filled is not representative of a typical compounded batch and the current practice as recorded in written reports of media fills do not address the need to incorporate worst case activities and challenging conditions.

OBSERVATION 2

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

Specifically:

Observation of aseptic operations found evidence of poor gowning practice in that of the two pharmacists involved in compounding operations, one was observed to be reaching into a bag of sterile components with the cuff of (b) (6), (b) (7)(C) sterile glove below the end of the gown sleeve and (b) (6), (b) (7)(C) wrist was visible. The other pharmacist was observed to have (b) (6), (b) (7)(C) mask gradually moving down (b) (6), (b) (7)(C) nose and throughout a long period of the compounding operation the mask continued to slide further down (b) (6), (b) (7)(C) nose. In the case of the latter referenced individual, (b) (6), (b) (7)(C) made numerous efforts to correct the mask using (b) (6), (b) (7)(C) gloved hand and did not make an effort to re-gown as necessary to correct the problem.

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OBSERVATION 3

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

Specifically:

Observation of aseptic operations from beginning to end found that the individual responsible for active viable sampling conducted all air sampling after operations were completed and without personnel present rather than performing it during operations.

The firm's environmental monitoring and personnel monitoring procedures state that (b) (4) Inspection found that the firm is not following their own procedures and TSA plates incubated in-house as well as TSA plates submitted to an external laboratory are incubated only at about (b) (4) centigrade for growth and recovery of aerobic bacteria.

There is no documented monitoring of the temperature of the incubator used for the incubation of active air sampling TSA plates.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically:

Compounded batches of drug products are not tested for potency.

OBSERVATION 5

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<p>Each batch of drug product purporting to be pyrogen-free is not laboratory tested to determine conformance to such requirements.</p> <p>Specifically:</p> <p>Compounded batches of drug products are not tested for endotoxin.</p>					
<p>OBSERVATION 6</p> <p>The labels of your outsourcing facility's drug products are deficient.</p> <p>Specifically:</p> <p>The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) and (B). Specifically,</p> <p>Your outsourcing facility's drug product labels do not contain a list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Examples of drug products labels that do not contain this information:</p> <ul style="list-style-type: none"> ○ Oxytocin 20 Units added to 1000 mL Lactated Ringers Injectable Bag ○ Cefazolin 1 gram added to 50 mL D5W Injectable Bag ○ Cefazolin 2 gm in 10 mL of 0.9% NaCl Injectable Syringe ○ Penicillin G Potassium 2.5 Million Units in 100 mL of D5W Injectable Bag ○ Bivalirudin 250 mg in 50 mL D5W Injectable Bag ○ Ceftriaxone 1 gm in 50 mL D5W Injectable Bag ○ Ceftriaxone 2 gm in 50 mL D5W Injectable Bag ○ Ampicillin-Sulbactam 3 gm in 100 mL 0.9% NaCl Injectable Bag ○ Ampicillin-Sulbactam 1.5 gm in 100 mL 0.9% NaCl Injectable Bag ○ Piperacillin-Tazobactam 3.375 gm in 50 mL D5W Injectable Bag 					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Robert C Horan, Investigator </td> <td style="width: 40%; vertical-align: top;"> <div style="text-align: right;"> <small>DATE ISSUED</small> 6/1/2017 </div> <div style="text-align: center;"> X Robert C Horan <small>Robert C Horan Investigator Signed by: Robert C. Horan -S</small> </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Robert C Horan, Investigator	<div style="text-align: right;"> <small>DATE ISSUED</small> 6/1/2017 </div> <div style="text-align: center;"> X Robert C Horan <small>Robert C Horan Investigator Signed by: Robert C. Horan -S</small> </div>
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OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically:

Your outsourcing facility did not submit a report to FDA identifying products compounded during the previous six months for the December 2016 reporting period as required by section 503B(b)(2)(A). Specifically, the following products, as examples, were compounded between June 1, 2016, and November 30, 2016, but were not identified on your report dated December 20, 2016:

- Ceftriaxone 2 gm in 50 mL D5W Injectable Bag
- Aztreonam 2 gm in 50 mL D5W Injectable Bag
- Ceftazidime 1 gm in 50 mL D5W Injectable Bag
- Pantoprazole 40 mg in 100 mL 0.9% NaCl Injectable Bag
- Ampicillin 1 gm in 50 mL D5W Injectable Bag

***DATES OF INSPECTION**

5/15/2017(Mon),5/17/2017(Wed),5/19/2017(Fri),5/22/2017(Mon),5/24/2017(Wed),6/01/2017(Thu)

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