

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 5/30/2019-6/25/2019*
	FEI NUMBER 3015452722

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Estee Altman, CEO

FIRM NAME Infusion Options, Inc.	STREET ADDRESS 745 64th Street
CITY, STATE AND ZIP CODE Brooklyn, NY 11219-4934	TYPE OF ESTABLISHMENT INSPECTED Warehouse

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

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

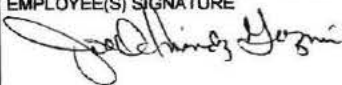
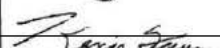
Specifically, on 05/30/2019, we observed ^{(b)(4)} boxes of drug products within expiry, stored on the floor of the pharmacy compounding room under filthy and uncontrolled temperature/humidity conditions. This facility is considered an "inactive compounding pharmacy", which is not maintained clean with the presence of dead insects and dirty floors within the drug storage room and at the moment of the inspection there were no temperature controls to assure that the drug products were maintained in adequate storage conditions. Some of the drug product found under these conditions include but not limited to:

- Oxaliplatin Injection 50mg/10mL, Lot#(b) (4) Exp: 07-2020
- (b) (4) (bortezomib) for Injection 3.5mg/vial, Lot#(b) (4) , Exp:05-2020
- Placitaxel Injection, USP 30mg/5mL, Lot#(b) (4) , Exp:07-2020
- (b) (4) for Injectable Suspension, 100mg/vial, Lot#(b) (4) , Exp:04-2021

Note: Due to your firm's lack of document control for the receipt, inventory, storage and use of these drug products there is no assurance on how long these drug products were exposed to the conditions aforementioned.

*Dates of Inspection: 05/30/2019(Thu), 05/31/2019(Fri), 06/05/2019(Wed) & 06/25/2019(Tue)

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jose O. Hernandez-Guzman, Investigator	DATE ISSUED 06/25/2019
		Kevin Flessa, Chemist	