DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, New York 11433 718-340-7000 Industry Information: www.fda.gov/oc/industry	7/20, 7/21, 7/22, 7/25, 7/26, & 8/1/2016
	FEI NUMBER 3008846597

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joseph Staniliwicz, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Alexander Infusion LLC dba Avanti Health Care Services	75 Nassau Terminal Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
New Hyde Park, New York, 11040	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) (WE) OBSERVED:

1. Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions, in that:

Smoke studies have not been conducted under dynamic conditions and mimicking the most challenging preparations produced by personnel on a regular basis to verify that operators, processing equipment or activities of the ISO 7 clean rooms do not alter or impede the unidirectional flow of air from the HEPA filters and for the (b) (4) ISO 5 laminar flow hoods where drug products are aseptically processed.

2. There is no written testing program designed to assess the stability characteristics of drug products. Specifically:

There is no written stability program to support assigned expiration dates for sterile preparations. Sterile preparations have never been tested for potency.

3. Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform, in that:

Non-sterile gowns are used to produce sterile preparations. The operator was observed having (b) (6), (b) (7) (C) head, some exposed facial skin & shoulders and arms entering the ISO 5 laminar flow hood while wearing a non-sterile gown, non-sterile mask and non-sterile head cover during compounding operations. Additionally, the operators working in the (b) (4) Room, still do not have sterile sleeves for their gowns, a deficiency observed during the previous inspection. This is a repeat deficiency from the previous inspection and corrective action has not been yet implemented..

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

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		DEMITRIA JENNY XIRADAKIS, INVESTIGATOR	8/1/2016

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(a) Personnel monitoring consists of fingertip sampling of gloves conducted (b) (4) ; not at least once daily during operations.

(b) Environmental monitoring for viable air counts in the ISO 5 area is not performed at least daily during periods of production. The firm only monitors viable air counts (b) (4) .

(c) The work surfaces, inside the ISO 5 hoods, are not tested for microbial contamination at least daily during periods of production and at the end of operations. This monitoring is only performed (b) (4) .

5. Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements, in that:

Sterility testing of preparations utilizes a (b) (4) whose instructions require an incubation temperature of (b) (4) not the (b) (4) being used (b) (4) since days incubated is not documented. The (b) (4) also requires the use of (b) (4) growth media however there is no documentation of the type of media & lot number utilized, and management has stated they have been unable to obtain the growth media. Additionally, a representative sample of all products prepared at your facility has not been tested, since the (b) (4) products are always tested (b) (4) which are (b) (4) . Sterility testing has also not been validated to show that antibiotic preparations at your firm, such as penicillin do not inhibit growth.

6. Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written, and followed, in that:

Media fill simulations have not been conducted under dynamic conditions mimicking the most stressful or challenging preparations/ worst case scenarios encountered by personnel producing sterile products on a regular basis to verify that operators, processing equipment or activities of the ISO 7 clean rooms do not alter or impede the unidirectional flow of air from the HEPA filters and for the (b) (4) ISO 5 laminar flow hoods where drug products are aseptically processed.

7.Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and

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equipment to produce aseptic conditions. Specifically:

There is no established contact time for the sporicidal agent used to disinfect the aseptic processing areas.

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