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 11433-1034 (718) 340-7000 Industry Information: www.fda.gov/oc/industry	6/23, 6/24, 6/25 & 7/09/2014
	FEI NUMBER 3008846597

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joseph Stanilewicz, 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	Outsourcing Facility

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 systems for maintaining any equipment used to control the aseptic conditions.

Specifically:

a). Smoke studies were not performed under dynamic conditions to verify that operators, processing equipment or activities of the ISO 7 clean rooms do not alter or impede the unidirectionality of air from the HEPA filters in the (b) (4) ISO 5 laminar flow hoods where drug products are aseptically processed.
b). There are no wall mounted room pressure monitors to monitor differential air pressures of the (b) (4) ISO 7 clean rooms, the ISO 7 anteroom, and the unclassified surrounding areas during production. There is no monitoring of pressure differentials at all.

OBSERVATION 2

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

a). Sterile drug products are aseptically manipulated by the clean room operators who were observed wearing non-sterile gowns, non-sterile pants, non-sterile and non-disinfected glasses/goggles, non-sterile footwear, non-sterile facial masks, and non-sterile bonnets. Operator's personal glasses are never changed, never disinfected. Operator's goggles, which are not disinfected, are changed only (b) (4).
b). The operator's face and neck are not fully covered allowing exposed facial skin and hair over the critical ISO 5 laminar flow areas where sterile injectable drug products are processed.
c). Gowning apparel and the rest of the operators' attire are composed of particle shedding materials.

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d). An operator was observed exiting the chemo (hazardous) clean room, then removing the gown and discarding it while in the adjacent clean room. These actions could potentially disperse particles in that clean room where other sterile injectable drug products are processed by exposing the underlying non-sterile and particle shedding scrubs.
e). The procedure operators use to put on sterile gloves used at the chemo ISO 5 work area is performed in a way as to risk contamination, since non-sterile chemo gloves are used to handle sterile gloves. The chemo gloves are not disinfected prior to placing sterile gloves over them.

OBSERVATION 3

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

Specifically,

a. Environmental monitoring for viable air counts in the ISO 5 zones is not performed at least daily during periods of production. The firm only monitors viable air counts [(b) (4)] in-house with a passive media paddle (settling plate) and [(b) (4)] by an outside vendor; lastly on 2/10/14.
b. Environmental monitoring for non-viable particulates in the ISO 5 zones is not performed under dynamic conditions. This was last performed on 02/10/14.
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)].
d. Operators' gloves are not tested for microbial contamination at least daily during periods of production. Glove fingertips are only monitored [(b) (4)].

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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 wipes are used to disinfect the ISO 5 hoods' sterile processing surfaces and they are composed of particle shedding material.
b. The firm does not use sporicidal agents to disinfect the ISO 5 surfaces.

OBSERVATION 5

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

No media fills/process simulations have been performed under the most stressful or challenging conditions. No media fills/process simulations have been done at all.

OBSERVATION 6

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

Specifically, given the observed inadequate environmental controls, testing is deficient in that:

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Your firm has not conducted valid sterility testing for any prescription orders that were filled. Only (b) (4) lots, of approximately (b) (4) lots of sterile injectable drugs processed per month, are tested by a non-compendial method that has not been validated to demonstrate equivalency to compendial methods.

OBSERVATION 7

The operations relating to the processing and packing of penicillin are not performed in facilities separate from those used for other drug products for human use.

Specifically,
a). Your firm is processing Penicillin-type injectable drugs, such as Penicillin, Nafcillin, and Oxacillin, in the same ISO 5 hood and cleanroom with your non-penicillin products. The absence of a structurally isolated area creates the potential that accidental breakage of vials of penicillin powders could contaminate your other sterile drug products.
b). There is no separate air handling system for penicillin drugs.

OBSERVATION 8

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

Specifically, there are no separate facilities, for processing operations, to prevent contamination from beta-Lactam non-penicillin injectable drugs, such as Cefaloin, Ceftazidime, and others. These beta-Lactam powders, which are contained in (b) (4) vials, are processed in the same ISO 5 hood and in the same clean room as sterile injectable non beta-Lactam drugs. There is no assurance that a potential breakage of the glass vial and consequent powder spill would not contaminate other sterile drug products.

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OBSERVATION 9

For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product.

Specifically, 100% visual checks of sterile injectable drugs for clarity/discoloration or particulates/contaminants are not performed. [redacted] (b) (4) of each lot, regardless of total units, is examined for product contamination.

OBSERVATION 10

An adequate number of batches of each drug product are not tested nor are records of such data maintained to determine an appropriate expiration date.

The firm's assigned Beyond Use Date (BUD) exceeds the shortest expiry date of the commercially available product when reconstituting sterile powders. The firm has not conducted any testing to support the longer BUDs and could not provide scientifically valid justification.

OBSERVATION 11

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A).

Specifically,

a. The lot numbers, information to facilitate adverse event reporting and the statements, "This is a compounded drug," and "Not for Resale," are not on your drug product labels for the following products:

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i. PACLITAXEL 100 MG(16.7 ML) 250 ML SOD CHL
ii. OXALIPLATIN 202 MG(40.4 ML) 500 ML D5W
iii. PACLITAXEL 112 MG (18.7 ML) 250 Ml SOD CHL
iv. PACLITAXEL 254 MG (42.3 ML) 500 Ml SOD CHL
v. DOXORUBICIN 92 MG (46 ML) SYRINGE
vi. CYCLOPHOSPHAMIDE 920 MG (46 ML) 100 ML
vii. DOXETAXEL 88 MG (4.4 ML) 250 ML SOD CHL
viii. OXALIPLATIN 150 MG (30 ML) 500 ML D5W
ix. MEROPENEM 1 GRAM IN 100 MLS 0.9 NS
x. PACLITAXEL 145 MG (24.1 ML) 250 Ml SOD CHL
xi. HYDROMORPHONE 1 MG/ML 250 ML
xii. INVANZ 1 GRAM IN 100 MLS 0.9 NS
xiii. DOCETAXEL 116 MG (5.8 ML) 250 ML SOD CHL
xiv. CARBOPLATIN 729 MG (72.9 ML) SOD CHL
xv. DEFEROXAMINE 2 GRAMS/18 ML SOLUTION

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."