DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration 4040 N. Central Expy Ste 300 Dallas, TX 75204 214-253-5200 Industry Information: www.fda.gov/oc/industry	24 - 28 July 2017
	FEI NUMBER 3010836489

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Sara A. Herrington - President and Owner

FIRM NAME	STREET ADDRESS
I.V. Specialty Ltd.	3200 Steck Ave., Suite 330
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Austin, TX 78757	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:

OBSERVATION 1

Vermin was observed present in areas immediately adjacent to your production area.

A dead spider was observed in HEPA filter located in the ceiling of the ISO 7 clean room, approximately 10 feet from the ISO 5 laminar air flow (LAF) hood used for sterile drug processing.

OBSERVATION 2

The ISO-classified have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

A. LAF Hood (b) (4) has loose panels covering a light fixture directly above aseptic processing area creating a difficult to clean surface. This equipment is intended to create an ISO 5 aseptic processing environment for sterile drugs.
B. LAF Hood (b) (4) has a loose access panel immediately below processing table surface that creates a difficult to clean surface. This equipment is intended to create an ISO 5 aseptic processing area.
C. Dirt, debris, stains, and one strand of hair proximately 2 inches long was observed in the front recirculation vent immediately below the aseptic processing surface of the ISO 5 hood.
D. LAF Hood (b) (4) is installed on a wood fiber board table with stainless steel, painted, and formica-type surfaces. This multi-surface table creates a difficult to sanitize surface in the clean room.
E. There is a office style telephone that creates a difficult to sanitize surface in the clean room. The wiring for the telephone was observed on the floor behind the shelf, creating a difficult to clean space in the ISO 7 room.
F. The supply and return air ducts are both located in ceiling of the clean room as well as the ante room. Your pharmacist stated this room is intended to meet ISO 7 and ISO 8 environment standards respectively.
G. The door to the ISO 7 clean room is constructed of a wood laminate approximately 15 feet away from the ISO

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		Scott Ballard, Investigator Nimmy Mathews, Investigator	07/28/2017

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5 LAF Hood used for processing sterile drugs. This wood laminate creates a difficult to sanitize surface in the clean room.
H. The ceiling of the ISO 7 clean room has a tear in the plastic surface of the drop-ceiling tile approximately 13 feet from the LAF Hood used for processing sterile drugs. This tear exposes the dry-wall material behind the plastic layer.

Note: Items C, D, E, F, and G are repeat observations from the Inspection in February 2016

OBSERVATION 3

Aseptic practices in critical area are not adequate for sterile drug processing. On 25 July 2017, we observed:

A. The pharmacist touching item on floor and return to processing TPN products without changing gloves.
B. The pharmacist using a bar code scanner from outside hood and return to processing without sanitizing gloves.

OBSERVATION 4

Cleaning or Sanitizing of ISO 7 clean room is not adequate. On 25 July 2017, we observed:

A. Pharmacist did not use a top-down approach to daily cleaning, the floor was cleaned first, then preparation tables. The bottom shelf of the preparation table was not sanitized where the (b) (4) pump is stored and the legs of the (b) (4) pump were not sanitized.
B. The container labeled "Sterile Water" in the clean room is not sterile. Additionally, the container does not have an expiration date, instead a fill date is written on the container. Your pharmacist stated that he fills the bottle with sterile water (b) (4) and uses it to clean "caked" on residue after production in the LAF hood and clean room.
C. The sanitized used in the ISO 7 and ISO 8 rooms ((b) (4))is a non-sterile disinfectant.

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OBSERVATION 5

Sterility Assurance is not adequate

Surface samples collected inside the ISO 5 LAF Hood on (b) (4) basis are not incubated at (b) (4)C per manufacturer instruction. We observed the plates being incubated at "(b) (4) " without an incubator at approximately (b) (4) C.

OBSERVATION 6

ISO-5 classified areas were not certified under dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions, based on video dated October 5, 2016 and titled 20161005_104749.mp4

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