DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314 Industry Information: www.fda.gov/oc/industry	08/20 - 31/2018
	FEI NUMBER 3014498447

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ernesto F. Garza-Gongora, Pharm. D., Pharmacist-In-Charge and Owner

FIRM NAME	STREET ADDRESS
Inventive Infusion Solutions, LP	18866 Stone Oak Pkwy Ste 101a
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Antonio, TX 78258-4181	Producer of Sterile and Non-Sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION # 1
Biological indicators are not used properly to verify the adequacy of the sterilization cycle.

Specifically,

Your firm relies on (b) (4) when (b) (4) sterilizing pellet drug product such as Testosterone 75 mg in (b) (4). Your firm does not use biological indicators (BIs) to verify the adequacy of the (b) (4) sterilization cycle. You do not place BIs in the (b) (4) (b) (4) used to house the pellets. BIs are not processed or subjected to the same conditions as the pellets therefore there is no assurance that the (b) (4) cycle parameters utilized to sterilize the pellets are adequate.

OBSERVATION # 2
Endotoxin level is not tested on the finished drug products.

Specifically,

You have no assurance that the endotoxin level of your intrathecal drug products is safe, since you do not have any endotoxin data and your firm doesn't perform endotoxin testing for the finished product. These preparations are made using non-sterile starting material. Furthermore, there is no endotoxin testing data for your bulk drug substances.

Add Continuation Page

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OBSERVATION # 3
Non-sterilized and Non-depyrogenated equipment was used in sterile drug production.
Specifically,

Your firm depyrogenated glassware and equipment inside the (b) (4) within the unclassified area. The (b) (4) is being used to store glassware and equipment that are purported to be depyrogenated. You indicated that the glassware and equipment can be stored inside the (b) (4) indefinitely until use. Your firm has not established the hold time for the purported to be depyrogenated glassware and equipment to ensure that they are pyrogen free before use. The glassware and equipment are used to weigh bulk drug substance powder and mix solution.

For example, the following drug products are produced using glassware.
1. Hydroxyprogesterone Caproate 250mg/ml Injection
2. HCG 1,000U/ml Injection
3. LIPO B Injection

OBSERVATION # 4
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

Your firm does not use the depyrogenated glassware and equipment during the media fills to simulate the aseptic production operations within your facility. The glassware is used by your firm to weigh out bulk drug substance for producing sterile drug products.

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OBSERVATION # 5
Personnel did not disinfect to prevent contamination

Specifically,

On 8/22/2018 and 8/28/2018, operator (b) (6) was observed with exposed facial skin while cleaning the surfaces inside the ISO 5 area of (b) (4) Hood. The cleaning processes within the ISO 5 area are the same for the (b) (4) and (b) (4) operations of (b) (4).

OBSERVATION # 6
You produced beta-lactam drugs without providing adequate containment, segregation, cleaning of work surfaces, cleaning of utensils and cleaning of personnel to prevent cross-contamination.

Specifically,

Your firm does not have a specific written process and procedure to describe the handling and cleaning of Beta-lactam productions within the ISO 5 areas. Your firm does not document the cleaning and disinfectant solutions used after production to ensure that the work surfaces are cleaned adequately to reduce the potential of cross contamination of Beta-lactam such as Ceftazidime 25mg/ml ophthalmic solution and Ceftazidime 50mg/ml otic solution. The ISO 5 areas are shared between the Beta-lactam and other drug products.

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OBSERVATION # 7
Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically,

On 08/24/2018, I observed visible gaps of approximately 0.5 cm between the HEPA filter grate panel and the ceiling panel frame and between the ceiling panel and the wall panel inside the ISO 7 clean room. These gaps are above the ISO 5 (b) (4) Hood that is being used for aseptic processing and (b) (4) sterilization processes. The ISO 5(b) (4) Hood was observed being used by operator(b) (6) to produce HCG 1,000U/ml Injection lot # 08242018@10.

OBSERVATION # 8
Disinfecting agents and used in the ISO 5 classified aseptic processing areas were note sterile.

Specifically,

Your firm is using the non-sterile (b) (4) Disinfectant Solution to disinfect surfaces within the ISO 5 areas. For example, on 08/22/2018, I observed operator(b) (6) cleaning the two ISO 5 areas with (b) (4) Disinfectant Solution.

UL 08/31/2018

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