DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT 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	11/09/2015 - 11/25/2015* FEI NUMBER 3011887629

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Arta Shaun Noorian, Owner

FIRM NAME	STREET ADDRESS
Empower Clinic Services, LLC	12123 Jones Rd
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Houston, TX 77070-5208	Producer of Sterile Drug Products

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 WE OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, the sterility test dated 9/10/15 which was conducted by your contract laboratory determined that Lipo-C Injectable, lot #17478 (Production date: 8/12/15, Beyond Use Date: 1/31/16) was not sterile. Subsequent speciation via (b) (4) [redacted] dated 9/22/15 which was also performed by the contract laboratory determined that the contaminating organism was *Streptomyces galbus*. An investigation performed by the contracting laboratory dated 9/3/15 documented that the source of the contamination was caused by "external error". A second sample tested for sterility from the same lot passed sterility testing.

There was no documentation of an investigation by your firm into the initial failing sterility result or potential impact on lots of injectable drug products produced on the same date. For example, the following lots of injectable drug products were also produced on 8/12/15:

- Glutathione, 200mg/ml, lot #17477
- GHRP-2/GHRP-6/Sermorelin, lot #17475
- GHRP-2/GHRP-6/Sermorelin, lot #17473

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

A) Media Fills

SOP #T08.06 entitled, "Sterile Compounding Process Validation " (Undated) documents, in part, that a total of (b) (4) [redacted] (b) (4) will be used to conduct media fills.

1) Review of media fills conducted between 8/4/14 and 10/2/15 revealed that the media fills were not representative of actual production processes in that:

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a. The media fills failed to simulate a lot with the maximum number of vials (i.e. (b) (4) vials)
b. The number and type of interventions was not included (i.e. breaks in processing to clean up spillage)
c. The aseptic assembly of equipment (e.g., at start-up, during processing) was not included.
d. The preparation/formulation of the API was not simulated.

2) Media fills for lyophilized products were not conducted (i.e. Human Chorionic Gonadotropin and Sermorelin)

B) (b) (4) Sterilization

Your firm uses a (b) (4) (Model (b) (4)) (b) (4) to sterilize rubber stoppers, caps, and forceps (b) (4) (b) (4) used: (b) (4)). SOP #T08-09 entitled, "(b) (4) Validation" (undated) documents that a (b) (4) (b) (4) However, (b) (4) has not been performed to demonstrate the (b) (4) (b) (4) .

C) (b) (4)

Your firm uses a (b) (4) for the depyrogenation of glassware ((b) (4)) used in the production of sterile, injectable drug products. The validation of the (b) (4) consisted of the (b) (4) (b) (4) to simulate worst case conditions (i.e. (b) (4)). However, (b) (4) (b) (4) (b) (4) have not been conducted to determine the (b) (4) .

D) Lyophilizer

Your firm utilizes a (b) (4) (b) (4) (Model (b) (4)) for the lyophilization of injectable drug products. Your firm failed to validate the (b) (4) used for the lyophilization of the drug products such as Human Chorionic Gonadotropin Lyophilized and Sermorelin. The specific (b) (4) used consist of the following:

(b) (4)

OBSERVATION 3

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

Specifically,

A. Viable air sampling is performed in the (b) (4) (b) (4) (b) (4)

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(b) (4) (b) (4)).

B. Microbiological monitoring of the employees' gloved fingertips is performed (b) (4) Monitoring is not performed during production for every lot of injectable drug product.

C. Microbiological monitoring of the (b) (4) is performed (b) (4) (Last date: (b) (4)) (b) (4) Monitoring is not performed at the completion of production for every batch produced.

OBSERVATION 4

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

Specifically,

A. Your firm has no documentation to justify the Beyond Use Date of injectable drug products for up to 365 days. For example,

- Cyanocobalamin, lot #17650 (Production date: 8/21/2015 Beyond Use date: 8/20/2016): 365 days
- Tri-Mix (Lyophilized) 150mg/5mg/50mcg/vial Injectable, lot #18514 (Production date: 10/2/2015, Beyond Use Date: 3/30/2016): 180 days

B. Your firm has not conducted anti-microbial effectiveness testing to determine whether (b) (4) will effectively inhibit microbial growth in sterile injectable drug products through BUD. For example,

- Cyanocobalamin, lot #17650 (Production date: 8/21/2015 Beyond Use date: 8/20/2016): Contains (b) (4)
- Glutathione (10ml) 200mg/ml Injectable, lot #17477 (Production date: 8/12/2015, Beyond Use Date: 2/8/2016): Contains (b) (4)

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OBSERVATION 5

Aseptic processing areas are deficient regarding systems for maintaining any equipment used to control the aseptic conditions.

Specifically,

A. Your firm checks and documents the (b) (4) (b) (4). There are no requirements for additional monitoring.

B. The sliding glass doors used between the rooms in the controlled and uncontrolled areas are not alarmed.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, your firm has not conducted disinfectant effectiveness studies to demonstrate that the disinfectants used to clean the walls, floors, ceilings, and work surfaces in the ISO 5, 7, and 8 areas can sufficiently reduce bioburden. Currently, your firm uses the following disinfectants in the ISO 5, 7, and 8 areas:

(b) (4)

In addition, your firm utilizes a (b) (4) (b) (4) to sanitize the interior of the ISO 7 and 8 rooms (b) (4) (b) (4). Your firm has not generated any data to demonstrate that the (b) (4) used effectively reduces bioburden.

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OBSERVATION 7

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically, prior to lyophilization, your firm (b) (4) (b) (4) (b) (4) However, your firm has not generated smoke studies to demonstrate that the ingress of air into the lyophilizer does not occur.

*** DATES OF INSPECTION:**
11/09/2015(Mon), 11/10/2015(Tue), 11/11/2015(Wed), 11/12/2015(Thu), 11/13/2015(Fri), 11/23/2015(Mon), 11/25/2015(Wed)

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