DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	4/10/2017-5/11/2017* FEI NUMBER 3011837323

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Kristin C. Comella , Chief Scientific Officer

FIRM NAME	STREET ADDRESS
US Stem Cell Clinic, LLC	12651 W Sunrise Blvd Ste 104
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sunrise, FL 33323-0906	Biological Drug Manufacturer

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

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

Specifically,

Your firm recovers autologous adipose tissue and manufactures Stromal Vascular Fraction (SVF) from this adipose tissue. During the period 12/08/2015-4/17/2017, your firm has manufactured at least (b) (4) batches of injectable SVF product. Your firm has failed to validate and document your aseptic manufacturing process or to establish written procedures to prevent microbial contamination of the injectable SVF product. Injectable SVF batches manufactured at your firm are administered by various methods to include intrathecal, intravenous (IV), intradiscal, intramuscular, or intra-articular.

This is a repeat deficiency that was listed as Observation #1 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

OBSERVATION 2

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically,

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Your firm has failed to perform sterility and endotoxin testing on at least (b) (4) batches of injectable SVF product manufactured between 12/08/2015-04/17/2017. Injectable SVF batches manufactured at your firm are administered by various methods to include intrathecal, IV, intradiscal, intramuscular, or intra-articular.

This is a repeat deficiency that was listed as Observation #2 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

OBSERVATION 3

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

Specifically,

Your firm does not perform any environmental monitoring in the aseptic processing area where the injectable SVF product is manufactured.

OBSERVATION 4

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

Specifically,

a. Your firm fails to use disinfectant agents that are appropriate for use for cleaning the (b) (4) (b) (4) the (b) (4) and the (b) (4) (b) (4) which are located inside the aseptic processing area. For example, your firm uses non-sterile (b) (4) and non-sterile wipes. Also, your firm does not use a sporicidal agent.

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b. Your firm has not established any cleaning or maintenance procedures for the (b) (4) (b) (4) the (b) (4) or for the (b) (4) (b) (4) Your firm is lacking records reflecting that cleaning, sanitizing, and inspections of equipment have been performed prior to, during, or after the manufacture of each batch of injectable SVF product. *This is a repeat deficiency that was listed as Observations #9 and #10 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.*

c. On 5/3/2017 we observed an accumulation of dust on two air vents in the room where the injectable SVF product is manufactured.

OBSERVATION 5

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

Your firm is using a (b) (4) manufactured by (b) (4) model (b) (4) during the manufacture of the SVF product. This (b) (4) has not been certified to facilitate operations for its intended use. The operations manual for this (b) (4) specifically states it is not intended for sterile compounding applications.

OBSERVATION 6

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

Specifically,

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Your firm has failed to ensure that employees engaged in the processing of the injectable SVF product wear clothing appropriate to protect the drug product from contamination. For example, non-sterile surgical masks, disposable shoe covers, and bouffant caps are used. Also, sterile gowns or sleeves are not worn during the processing of the injectable SVF product.

OBSERVATION 7

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

Your firm (b) (4) he cellular components from adipose tissue through (b) (4) (b) (4) You have failed to validate your SVF manufacturing process. This SVF manufacturing process requires the use of components including (b) (4) (b) (4)

OBSERVATION 8

Laboratory controls do not include the establishment of scientifically sound and appropriate specifications, sampling plans and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

a. The (b) (4) used in the manufacture of the injectable SVF product is for research use only, as stated on the manufacturer's product insert which was provided by your firm. In addition, the (b) (4) used in the manufacture of the injectable SVF product is not for human therapeutic use, as stated on the manufacturer's Certificate of Analysis. Your firm lacks evidence, such as testing, to demonstrate these components meet all specifications of identity, strength, quality, and purity.

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b. Your firm has failed to perform (b) (4) testing on the (b) (4) used in the manufacture of the injectable SVF product.

c. Your firm has not established written acceptance criteria for components or written procedures for sampling, testing, or examining each lot of components received and released for use in the manufacture of at least (b) (4) batches of injectable SVF product during the period 12/08/2015-04/17/2017. Components received and used by your firm to manufacture injectable SVF product include, but are not limited to (b) (4) (b) (4)

d. Your firm has not established a written procedure which describes the in-process and release criteria for the injectable SVF product.

Observations #3c and #3d are repeat deficiencies that were listed as Observation #3 on previous FDA-483, Inspectional Observations, dated 12/07/2015.

OBSERVATION 9

Written procedures are lacking which describe in sufficient detail the identification, storage, approval and rejection of components.

Specifically,

Your firm does not have written procedures detailing the identification, storage, approval and rejection of components including, but not limited to the (b) (4) (b) (4) used in the production of the injectable SVF product.

This is a repeat deficiency that was listed as Observation #4 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

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OBSERVATION 10

There is no quality control unit.

Specifically,

Your firm does not have an established quality control unit which has the responsibility and authority to approve or reject all components, in-process materials, procedures or specifications which could impact the identity, strength, quality, and purity of the injectable SVF product.

This is a repeat deficiency that was listed as Observation #7 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

OBSERVATION 11

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically,

Since 12/08/2015, your firm has manufactured at least (b) (4) batches of injectable SVF product. Your firm's production records are lacking information including, but not limited to, the specific lots of (b) (4) which were used to (b) (4) the stem cells, the start and stop times of the (b) (4) and the personnel performing each significant step in the manufacture of the injectable SVF product.

This is a repeat deficiency that was listed as Observation #6 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

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OBSERVATION 12

Procedures describing the handling of written and oral complaints related to drug products are not written or followed.

Specifically,

Your firm has failed to establish written procedures for handling complaints, including procedures to determine whether an investigation is needed. Four out of fifteen records reviewed had follow-up notes pertaining to possible complaints reported by the patients.

This is a repeat deficiency that was listed as Observation #8 on the previous FDA-483, Inspectional Observations, dated 12/07/2015.

*DATES OF INSPECTION

4/10/2017(Mon),4/12/2017(Wed),4/17/2017(Mon),4/19/2017(Wed),4/25/2017(Tue),5/03/2017(Wed),5/11/2017(Thu)

5/11/2017

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Investigator
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