DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 (718) 340-7000 Fax:(718) 662-5661 Industry Information: www.fda.gov/oc/industry	11/08/2011 - 12/12/2011* FEI NUMBER 3009237709

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Steven Victor, Medical Director

FIRM NAME	STREET ADDRESS
IntelliCell Biosciences, Inc.	30 East 76th Street 6th Floor
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10021	Human Tissue Establishment

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 OBSERVED:

OBSERVATION 1

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

Specifically,

Your firm recovers and processes adipose tissue (lipo aspirate) from autologous donors. The manufacturing of the Stromal Vascular Fraction including the Ultrasonic Cavitation is performed in the Laminar Flow Hood. The Stromal Vascular fraction is then injected to the patients intravenously or into other locations on their body such as lips, cheeks, knees, scalp and /or buttocks.

- You failed to validate and document your aseptic manufacturing process and establish operating procedures to prevent microbiological contamination of the Stromal Vascular Fraction.
- From August 2010 to November 2011, the Laminar Flow Hood microbiological swabbing was performed (b) (4), in June 2011. There were more than (b) (4) Autologous Stromal Vascular Fraction manufacturing procedures performed from August 2010 to November 2011.

OBSERVATION 2

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

Specifically,

The Stromal Vascular fraction manufactured at your firm is injected to the patients intravenously or into other locations on their body such as lips, cheeks, knees, scalp and /or buttocks.
Your firm failed to perform sterility testing on Stromal Vascular Fraction for more than (b) (4) Autologous Stromal Vascular Fraction products manufactured from August 2010 to November 2011.

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OBSERVATION 3

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,

a) During the Stromal Vascular Fraction manufacturing process, (b) (4) solution is added to the SVF. Your procedure does not specify how this reagent is prepared and used.

b) Your firm manufactures a Stromal Vascular Fraction using Ultrasonic Cavitation. The stem cells are separated from adipose fat by (b) (4). However, there are no procedures in place and no documentation maintained showing the validation and established working parameters for your Ultrasonic Processor.

c) The adipose aspirate (fat) "resting" time, Ultrasonic Cavitation time and the probe used, centrifugation time, and the amount of (b) (4) solution added are not documented at the time of performance for (b) (4) procedures performed from August 2010 to November 2011.

OBSERVATION 4

Established test procedures and laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

The adipose aspirate (fat) "resting" time, Ultrasonic Cavitation time and the probe used, centrifugation time, the amount of (b) (4) solution and (b) (4) added, and holding time after adding (b) (4) are not documented at the time of performance for (b) (4) procedures performed from August 2010 to November 2011.

OBSERVATION 5

Deviations from written production and process control procedures are not justified.

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The following changes were made to the established procedure entitled "Ultrasonic Cavitation of Processing Stem Cells from Adipose Tissue":

i) On 11/08/11, Ultrasonic Cavitation time was changed from (b) (4) minutes to (b) (4) minutes during the Stromal Vascular Fraction (SVF) manufacturing for patient (b) (6).

ii) A (b) mm rod was used to manufacture SVF (b) (4), and (b) mm rod was used to manufacture SVF (b) (4) for the same patient (procedure performed on 5/25/11). These SVFs were released and injected into the patient.

However, these deviations were not allowed by your procedure and were not justified by the Quality Control Unit.

OBSERVATION 6

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

Specifically,

a) Your firm did not establish a written procedure that describes Stromal Vascular Fraction (SVF) in-process and release criteria (b) (4) t. The SVF with viabilities ranging from (b) (4) % were released and injected to (b) (4) patients from August 2010 to November 2011.

b) A Stromal Vascular Fraction (b) (4). However, there are no procedures in place and no documentation maintained showing the validation and established working parameters for your Flow Cytometer.

c) During your quality control analysis, a (b) (4) is added to a portion of the Stromal Vascular Fraction manufactured. However, the holding times after adding (b) (4) are not documented at the time of performance for (b) (4) procedures performed from August 2010 to November 2011.

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OBSERVATION 7

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

Specifically,

Your firm utilizes (b) (4) solution to dilute Stem Cells during manufacturing of the Stromal Vascular Fraction. In addition, a Stromal Vascular Fraction manufactured is added to various amounts of (b) (4) solution and intravenously injected into the patients. However, there is no procedure in place that describes the receipt, identification, storage, and handling of this component. There were (b) (4) Stromal Vascular Fractions manufactured from August 2010 to November 2011.

OBSERVATION 8

The distinctive code for each lot of components and drug product containers is not used in recording the disposition of each lot.

Specifically,

Your firm failed to record the lot numbers of the following components and supplies utilized in manufacturing of the Stromal Vascular Fraction: (b) (4), syringes, 50mL centrifuge tubes and (b) (4) Units. These components and supplies were utilized for manufacture and used for (b) (4) patients from August 2010 to November 2011.

OBSERVATION 9

Procedures describing the handling of all written and oral complaints regarding a drug product are not established, written, and followed.

Specifically,

The Stromal Vascular Fraction manufactured at your firm is used to treat your autologous donors intravenously or through injections at various locations on the patient's body. These injections or procedures are performed by the physicians or by a dentist at your office. However, your firm did not establish any procedures that describe a process of documenting and investigation of complaints relating to your manufactured product.

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OBSERVATION 10

There is no quality control unit.

Specifically,

Your firm failed to establish a Quality Control Unit and procedures applicable to the Quality Control Unit in order to approve or reject manufacturing components, drug product containers, in-process materials, review production records, and to prevent, investigate and correct errors in manufacturing of the Stromal Vascular Fraction.

OBSERVATION 11

The control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

The Medical Assistant stated that the filter on the Laminar Flow Hood is periodically changed. However, there is no documented evidence of this activity. In addition, the temperature of the manufacturing/processing room is not monitored.

OBSERVATION 12

Records are not kept for the maintenance, cleaning, sanitizing, and inspection of equipment.

Specifically,

a) The Ultrasonic Processor and a Centrifuge is used during the manufacture of the Stromal Vascular Fraction (SVF). However, the maintenance records for this manufacturing equipment are not documented and maintained by your firm.

b) Your firm did not establish any cleaning and sanitizing procedures for the equipment and utensils used in manufacturing of Stromal Vascular Fraction. There are no documented records of sterilizing of the equipment and utensils used in manufacturing. On 11/08/11 and 11/09/11, the Medical Assistant could not provide the lot number and the expiration date of the cleaning reagent she was using to clean the Laminar Flow Hood before and after SVF manufacturing.

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OBSERVATION 13

Buildings used in the manufacturing and processing of a drug product are not maintained in a good state of repair.

Specifically,

Your manufacturing/processing area ceiling had three missing tiles exposing the building's ventilation system. The floor tiles had seams approximately half an inch wide preventing the floor from proper cleaning.

*** DATES OF INSPECTION:**
11/08/2011(Tue), 11/09/2011(Wed), 11/28/2011(Mon), 12/12/2011(Mon)

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