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	05/14/2013 - 06/06/2013* FEI NUMBER 3009842420

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Steven A. Victor, Medical Director

FIRM NAME	STREET ADDRESS
IntelliCell BioSciences, Inc.	460 Park Avenue 17th floor
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
New York, NY 10022	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

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 tested.

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

OBSERVATION 2

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a) *Your standard operating procedure #60.001 entitled "Quality Assurance Program Management" section 4.2 "Required Key Functions" describes Quality Assurance Director's responsibilities and states: "*(b) (4) "

From March 2012 to April 2013 your Quality Assurance Director manufactured or assisted in manufacturing of the Stromal Vascular Fraction of at least (b) (4) Stromal Vascular Fraction (SVF) products for the following donors: (b) (4), (b) (7)(C)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Irina Gaberman, Investigator	DATE ISSUED 06/06/2013

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(b) (4), (b) (7)(C) These batches were documented as approved and released by the same Quality Assurance Director.

b) Your standard operating procedure #40.001 entitled "Separating Stromal Vascular Fraction (SVF) from Lipo-Aspirate" states:

i) "(b) (4) ." On 5/17/2013, laboratory technician manufactured the SVF for donor (b) (7)(C) without an assistant. In addition, a review of the Manufacturing Batch Record Forms revealed that there were at least (b) (4) batches manufactured without an assistant from October 2012 to May 2013.

ii) "(b) (4) ." (b) (4) filters made by (b) (4) were used instead of (b) (4) filters during manufacturing of the following batches: (b) (4), (b) (7)(C)

c) Your standard operating procedure #30.001.WI.1 entitled "Cleaning the Isolator Hood" section 4 states: (b) (4)

On 5/17/2013, your lab technologist was observed using (b) (4) Wipes to disinfect the Isolator after manufacturing the SVF for donor (b) (7)(C) .

d) Your standard operating procedure #30.001.WI.2 entitled "Environmental Monitoring" states: "(b) (4) ". There was no documentation that environmental monitoring was performed for at least SVF batches manufactured from January 2013 to May 2013.

In addition, on 9/19/12, an expired (b) (4) plate was used for the environmental monitoring during SVF manufacturing for donor (b) (7)(C) .

OBSERVATION 3

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

Specifically,

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On 2/5/13, your firm manufactured the ear drops from the Lipo-Aspirate harvested on 2/1/13 from donor (b) (7)(C) . The Manufacturing Batch Record was approved and released by your Quality Assurance Director on 2/5/13. The Manufacturing Batch Record states: (b) (4) ." However, your firm does not have an established stability program for the Lipo-Aspirate and Stromal Vascular Fraction storage in the refrigerator for more than (b) (4) , and for the ear drops prepared from the SVF. Also, you do not have any established standard operating procedures to support the manufacturing of the ear drops from the SVF.

OBSERVATION 4

The establishment of specifications including any changes thereto, are not reviewed and approved by the quality control unit.

Specifically,

The performance qualification entitled "ES-VAL-PTS001-12" (Effective Date: 12-JUN-2012) of the (b) (4) Analyzer performed by the vendor was done in the operating range of (b) (4) EU/mL. However, your firm operated (b) (4) Analyzer in the range of (b) (4) EU/mL to measure Endotoxin level for the following Stromal Vascular Fraction manufactured batches: (b) (7)(C) .

OBSERVATION 5

Routine calibration of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a) Your standard operating procedure #60.002.WI.1 entitled "Guide to Equipment Operation and Maintenance" part III section 2 states: "(b) (4) ."
Your isolator was last calibrated in April 2012 and was past due for calibration. There were at least (b) (4) Stromal Vascular Fraction (SVF) products manufactured in your Isolator in May 2013 for the following donors: (b) (7)(C)

b) Your standard operating procedure #60.002.WI.2 entitled "Guide to Equipment Operation and Maintenance" states: "(b) (4) ."
Your (b) (4) calibration of the Centrifuge was performed on 5/8/12 by your Quality Assurance Director using a tachometer. Your standard operating procedure #60.002.WI.2 does not describe your calibration procedure using a

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tachometer and your calibration record failed to include the tachometer information such as day calibrated and name/manufacturer.

c) Your standard operating procedure #60.002.WI.6 entitled "Guide to Equipment Operation and Maintenance" states: "(b) (4) ."
Your autoclave was last calibrated in April 2012 and was past due for calibration that was scheduled for (b) (4) . However, the autoclave was still used to sterilize supplies for at least (b) (4) SVF batches manufactured in May 2013.

d) Your standard operating procedure #60.002.WI.4 entitled "Guide to Equipment Operation and Maintenance", "Pipette Maintenance Schedule" section, states: "(b) (4) ."
Your (b) (4) pipettes were last calibrated in April 2012 and were due for re-calibration on (b) (4) . Yet, these pipettes were used for at least (b) (4) SVF batches manufactured in May 2013.

OBSERVATION 6

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

Specifically,

On 5/7/12 you performed Isolator Hood (b) (4) Cleaning Validation Study 5.7.2012 with expected end result documented on the validation study as "(b) (4) ". (b) (4) out (b) (4) culture plates tested were positive for cultures: (b) (4) culture plate from "Pass Through Window" test result reported by the testing laboratory for this validation study was documented as (b) (4) CFU Coagulase Negative Staphylococcus and the (b) (4) culture plate (from Right Ceiling) test result was documented as (b) (4) CFU Bacillus Species Not Anthracis.
On 5/17/12 the second Isolator Hood (b) (4) Cleaning Validation Study 5.17.2012 was performed with expected end result documented on the validation study as "(b) (4) ". (b) (4) plates tested (from Bottom Left) was documented as (b) (4) CFU Coagulase Negative Staphylococcus.
On 7/26/12 the third Isolator Hood (b) (4) Cleaning Validation Study 5.17.2012 was performed with expected end result documented on the validation study as "(b) (4) ". There were (b) (4) plates tested (Bottom Left, Pass Through Door, and Top Right Ceiling). There were (b) (4) Stromal Vascular Fraction products manufactured between 5/7/12 and 7/26/12. In addition, the initials of the person performing Isolator Hood (b) (4) Cleaning Validation studies were not documented. All three validation study reports were approved by your Quality Assurance Director on 11/20/12.

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OBSERVATION 7

Procedures prescribing a system for reprocessing batches to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics are not written.

Specifically,

a) *On 3/12/13, the Stromal Vascular Fraction manufactured for donor* (b) (7)(C) was documented as re-worked. *This batch was released by your Quality Assurance Director on the same day. However, there is no procedure in place describing your re-work process.*

b) On 6/1/12, the SVF cell count measured by flow cytometer was documented as (b) (4) / ml and "did not meet release criteria" for the batch manufactured for donor (b) (7)(C) This batch was documented as "re-worked and released" by the Laboratory Technician on the same day. You do not have an established process for re-working the SVF batches.

OBSERVATION 8

Individuals responsible for supervising the manufacture and processing of a drug product lack the training to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically,

a) On 5/25/12 and on 6/2/12 (b) (4) Stromal Vascular Fraction batches were manufactured by your laboratory technician (b) (7)(C) for donors (b) (7)(C) . The quality assurance release of these SVF batches was approved by your laboratory technician (b) (7)(C) A review of the documented training records revealed that (b) (7) did not have adequate training and responsibility to release the SVF batches in May and June of 2012.

b) Your Quality Assurance Director approved and released at least (b) (4) Stromal Vascular Fraction batches manufactured from 3/21/12 to 4/17/2013. However, there are no documented evidence that this person has the knowledge and adequate training to approve and release your manufactured SVF products.

OBSERVATION 9

Established test procedures and laboratory control mechanisms are not followed.

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Your standard operating procedure entitled #40.002 entitled "QC Testing and QA Release of Autologous SVF Cells" states:
"(b) (4) ."

A review of your manufacturing batch records from May 2012 to May 2013 revealed that at least (b) (4) manufactured SVF batches did not have Endotoxin testing as required by your procedure. These batches were approved and released by your QA department and the SVF product was re-infused to the patients on the same day.

Donor #	Manufacturing Date	SVF Amount Released, cc	Approved by
(b) (7)(C)	9/11/12	(b) (4)	QA
(b) (7)(C)	9/19/12	(b) (4)	QA
(b) (7)(C)	4/8/13	(b) (4)	QA
(b) (7)(C)	4/18/13	(b) (4)	QA
(b) (7)(C)	4/30/13	(b) (4)	QA
(b) (7)(C)	5/1/13	(b) (4)	QA
(b) (7)(C)	5/4/13	(b) (4)	QA
(b) (7)(C)	5/13/13	(b) (4)	QA
(b) (7)(C)	5/13/13	(b) (4)	QA
(b) (7)(C)	5/17/13	(b) (4)	QA

OBSERVATION 10

Written procedures are lacking which describe in sufficient detail the sampling, testing, and approval 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 identification and testing of this component. There were at least (b) (4) Stromal Vascular Fractions manufactured from March 2012 to May 2013.

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OBSERVATION 11

Deviations from written specifications are not justified.

Specifically,

Your standard operating procedure entitled "Guide to Equipment Operation and Maintenance" states: "(b) (4) ". On 8/2/12, the Stromal Vascular Fraction manufactured for donor (b) (7)(C) was documented as diluted and tested at (b) (4) dilution after the Flow Cytometer gave a dilution warning for the (b) (4) dilution. This manufacturing batch was approved and released by your Quality Assurance Director on the same day.

OBSERVATION 12

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically,

Your standard operating procedure #40.002 entitled "Quality Assurance" states: "(b) (4) ". In addition, your standard operating procedure #40.001 entitled "Separating Stromal Vascular Fraction (SVF) From Lipo-Aspirate" states: (b) (4) ".

i) However, the following Manufacturing Batch Records were released from the manufacturing laboratory *without* the approval of the QA Director:

Donor ID Number	Tissue Recovery Date	Tissues Used
(b) (7)(C)	4/18/2013	yes
(b) (7)(C)	4/30/2013	yes
(b) (7)(C)	5/01/2013	yes
(b) (7)(C)	5/07/2013	yes
(b) (7)(C)	5/13/2013	yes
(b) (7)(C)	5/13/2013	yes

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ii) Gram Stain testing was not documented as performed for the batch (b) (7)(C), (b) (4) manufactured on 8/2/12. However, this batch was approved by the Quality Assurance Director and (b) (4) of SVF was released to donor (b) (7)(C) .

OBSERVATION 13

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

On 4/1/13, your autoclave sterilizer Biological Indicator (BI) strip testing was performed and on 4/4/13 the testing laboratory reported the test was "POSITIVE (not sterile) MUST RETEST IMMEDIATELY". The previous negative autoclave BI strip testing was performed on 3/26/13. There were (b) (4) batches manufactured from 3/27/13 to 4/4/13: (b) (4), (b) (7)(C) . These batches were released by QA. However, there was no thorough investigation performed to determine the effect of a failed BI strip testing on these released batches.

OBSERVATION 14

The use of instruments not meeting established specifications was observed.

Specifically,

a) On 1/3/13, endotoxin "Test Suitability" and "Sample Rxn Time CV" were documented as "Fail" on the (b) (4) Test Record for the Stromal Vascular Fraction manufactured for patient (b) (7)(C) . The SVF batch for donor (b) (7)(C) was approved and released by your Quality Assurance Director on the same day.
b) The (b) (4) Test Report performed for the Stromal Vascular Fraction indicated that "Sample not seen; inspect marked channel" for the following batches manufactured:

Donor #	Date Manufactured
(b) (7)(C)	12/06/12
(b) (7)(C)	1/23/13
(b) (7)(C)	1/29/13
(b) (7)(C)	4/5/13

However, Endotoxin test results were accepted, the batches were approved and released by your Quality Assurance Director.

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OBSERVATION 15

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

Specifically,

Your standard operating procedure #40.002 entitled "QC Testing and QA Release of Autologous SVF Cells" states: "(b) (4) [redacted] " On 7/9/12, Stromal Vascular Fraction batch was manufactured for donor (b) (7)(C) and the SVF product Endotoxin level tested was documented as (b) (4). There were no specific Endotoxin calculations documented for donor (b) (7)(C). The weight of the donor was not documented. There were no instructions regarding administration of the SVF product based on the endotoxin level documented on the (b) (7)(C) Manufacturing Batch Record. Yet, the SVF was released by the Quality Assurance for donor (b) (7)(C) use.

OBSERVATION 16

Failure to perform a thorough investigation of an unexplained discrepancy and a failure of a lot or unit to meet any of its specifications.

Specifically,

On 4/1/13, your autoclave sterilizer Biological Indicator strip testing was performed and on 4/4/13 the testing laboratory reported that it failed sterility testing. The previous negative autoclave sterility testing was performed on 3/26/13. There were (b) (4) batches manufactured from 3/27/13 to 4/4/13: (b) (4), (b) (7)(C) [redacted]. These batches were released by QA. However, there were no thorough investigation performed to determine the effect of a failed sterility testing on these released batches.

OBSERVATION 17

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

The Endotoxin testing is perofrmed for each manufactured Stromal Vascular Fraction batch using (b) (4) [redacted] Reader. However, the (b) (4) Test Record that is generated for each testing was not available for review for the following

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batch records: (b) (4), (b) (7)(C)

OBSERVATION 18

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically,

The cell count and cells viability testing performed on the finished product (Stromal Vascular Fraction) is part of your quality control testing prior to release of the product. A review of the flow cytometer cell analyzer reports from May 2012 to May 2013 revealed that the initials of the person performing this analysis on the flow cytometer and date performed were not documented on the analyzer reports. In addition, the second person review is not documented on the reports.

*** DATES OF INSPECTION:**
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