DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 orabioinspectionalcorrespondence@fda.hhs.gov	11/27/2023-12/8/2023* FEI NUMBER 3014621414

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kevin S. Jensen, V.P. of Quality

FIRM NAME	STREET ADDRESS
CellSure, L3C	615 Arapeen Drive Ste 300
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Salt Lake City, UT 84109	Stem Cell Own-Label Distributor

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

HCT/Ps for which the applicable donor eligibility requirements were not met were not prominently labeled with the appropriate warning statements.

Specifically, the following placenta and umbilical cord tissue intended for use in first- and second-degree relatives tested positive for Cytomegalovirus (CMV) and did not contain the statement "WARNING: Advise Recipient of communicable disease risks: Positive for CMV."

- (b) (4) vials in storage
- vials in storage
- vials in storage
- (b) (4) vials in storage
- (b) (4) all (b)(4) vials of placental stem cells were distributed on 01/21/2022.

OBSERVATION 2

Donors were not screened by a review of relevant medical records for risk factors of communicable disease agents and diseases.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily B Camire, Investigator Creighton T Tuzon, Investigator	X Emily B Camire Investigator Signed By: Emily B. Camire -S Date Signed: 12-08-2023 11:41:52	12/8/2023

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Specifically, from September 2021 to August 2023 your firm screened Donors and Clients that provided gestational tissue and recovered human umbilical cord and placenta tissues. Donors and Clients were not screened by a review of relevant medical records for risk factors of communicable disease agents and diseases. Donor and Client screening questions missing from the medical and social questionnaire, include the following:

- Persons who have tested positive or reactive for WNV infection using an FDA-licensed or investigational WNV NAT donor screening test in the preceding 120 days.
- Persons who have been diagnosed with vCJD or any other forms of CJD.
- Persons who have been diagnosed with dementia or any degenerative or demyelinating disease of the central nervous system, or other neurological defects of unknown etiology.
- Persons who are at increased risk for CJD.
- Persons who have a history of CJD in a blood relative.
- Residence in, or travel to, an area with an increased risk for ZIKA virus transmission at any point during pregnancy.

Since August 2021, your firm screened, processed, and stored approximately (b)(4) vials of placenta and umbilical cord tissue cryopreserved from (b)(4)) clients, of which (b)(4) vials in a segmented bag from one (1) Client was distributed on 21 JAN 2022. Your firm is currently storing placenta and umbilical cord tissue for (b)(4) clients.

This is a repeat observation.

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OBSERVATION 3
The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically, your firm has not established any specific criteria, specifications or procedures with respect to the processing of human placenta and umbilical cord tissue by a contract manufacturer, into frozen placenta and umbilical cord tissue for storage customers.

This is a repeat observation.

OBSERVATION 4
Procedures describing the warehousing of drug products are not established.

Specifically, your firm has not established procedures for the location and quality status of your inventory of approximately (b)(4) vials of placental stem cells stored in (b)(4) storage tanks by (b)(4) separate third parties under your administrative control.

This is a repeat observation

OBSERVATION 5
Written distribution procedures are not established.

Specifically, your firm has not established procedures for the distribution of your placental stem cell product. Your firm distributed (b)(4) vials of placental stem cells on 01/21/2023.

OBSERVATION 6
There is no written testing program designed to assess the stability characteristics of drug products.

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Specifically, your firm has not established a stability program to evaluate relevant criteria of placental stem cells stored at (b)(4) in segmented (b)(4) or (b)(4) relevant for items stored since August of 2021. Your firm is storing placental stem cells in at least two different media: (b)(4) and (b)(4) (b)(4) Your Chief Scientific Officer specifically stated that these products do not have an expiration date.

This is a repeat observation.

***DATES OF INSPECTION**

11/27/2023(Mon), 11/28/2023(Tue), 11/29/2023(Wed), 11/30/2023(Thu), 12/01/2023(Fri), 12/04/2023(Mon), 12/05/2023(Tue), 12/06/2023(Wed), 12/07/2023(Thu), 12/08/2023(Fri)

X Creighton T Tuzon
Investigator
Signed By: Creighton Tuzon -S
Date Signed: 12-08-2023 11:42:15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Emily B Camire, Investigator Creighton T Tuzon, Investigator	X Emily B Camire Investigator Signed By: Emily B. Camire -S Date Signed: 12-08-2023 11:41:52	12/8/2023

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."