DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	9/17/2018-9/21/2018
	FEI NUMBER 3013957857

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Erin M. Sairafe, Chief Compliance Officer

FIRM NAME	STREET ADDRESS
Liveyon	22667 Old Canal Rd
CITY, STATE, ZIP CODE, COUNTRY Yorba Linda, CA 92887-4601	TYPE ESTABLISHMENT INSPECTED own label stem cell 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

Adverse reactions which involved a communicable disease related to an HCT/P made available for distribution and were fatal or life threatening, resulted in permanent impairment or damage to the body, or necessitated medical or surgical intervention, were not reported to FDA.

Specifically, adverse reactions were not reported to FDA by the firm. For example:

A. AER-022018-01 reported an adverse reaction occurred 2/20/18 with patient (b) (6) Lot# (b) (4) and Lot#(b) (4) were injected into the knees and the patient experienced nausea and knee pain within 30 minutes, was hospitalized, and treated for possible Graft vs. Host Disease.
B. AER-022018-02 reported an adverse reaction occurred 2/20/18 with patient (b) (6) Lot# (b) (4) was injected into the knees and the patient experienced chest tightness and knee pain within 30 minutes, was hospitalized, and treated for possible Graft vs. Host Disease.
C. AER-080218-01 reported an adverse reaction occurred 7/26/18 with a patient (no initials provided). Lot (b) (4) was injected into the knee and the patient experienced discharge and high temperature. Post injection culture of knee fluid was positive for E. Coli.
D. AER-080218-02 reported an adverse reaction occurred 7/27/18 with patient (b) (6) Lot# (b) (4) was injected into the knee and shoulder and the patient

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experienced swelling and pain within 2 hours, was hospitalized 7/28 with emergency surgery to flush joint, and lab work was positive for E. Coli.

E. AER-080218-03 reported and adverse reaction occurred 7/27/18 with patient (b) (6) Lot# (b) (4) was injected into the ankle and the patient experienced swelling and pain within 24 hours, was hospitalized 7/30 with emergency surgery to flush joint, and lab work was positive for E. Coli.

F. AER-081718-01 reported an adverse reaction occurred 8/10/18 with patient (b) (6) Lot# (b) (4) (incorrect, lot # is (b) (4)) was injected into the knee and the patient experienced pain in 3 hours, was hospitalized for 5 days, joint aspirate cultured E. Coli and patient blood specimen cultured E. Coli.

G. AER-090418-01 reported an adverse reaction occurred 8/15/18 with patient (b) (6) Lot# (b) (4) was injected into the knee and the patient experienced knee pain after 1 ½ hours, was hospitalized, and lab work was positive for E. Coli.

OBSERVATION 2

Complaint records are deficient in that they do not include the findings of the investigation and follow-up.

Specifically, complaints and adverse events recorded on the AER-Complaint Log lack thorough follow up. For example:

A. When a complaint is determined to not require further investigation, this is not documented.
   1) Complaint 61818-01 for lot# (b) (4) which documents a patient experienced an adverse reaction that included in an ER visit and E. Coli positive specimen culture was not followed up. The reported reason is because this physician had injected 6 other patients with this same lot# with no adverse events experienced. (b) (4) vials were made of this lot.

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B. When physicians report complaints but do not complete an adverse reaction report, the AER-Complaint Log is the only record of the incident. In the following cases, the contract manufacturer was notified of the complaints but documents no investigation or follow up reported by the contract manufacturer:

1) Complaint 081018-01 for E. Coli on lot# (b) (4) vial (b) (4) was reported to the contract manufacturer on 8/14/18. There is no documentation of the contractor's investigation.
2) Complaint 081418-01 for severe pain in Lot#s (b) (4) via (b) (4), (b) (4) vial (b) (4), (b) (4) vial (b) (4), (b) (4) vial (b) (4), (b) (4) via (b) (4), (b) (4) vial (b) (4), (b) (4) via (b) (4). The complaint was reported to the contractor manufacturer on 8/14/18 and there is no documentation of contractor's investigation.
3) Complaint 051818-01 for severe pain and ER intervention on Lot#s (b) (4) vial (b) (4), (b) (4) via (b) (4), (b) (4) via (b) (4), (b) (4) vial (b) (4), (b) (4) vial (b) (4). The complaint was reported to contractor on 5/18/18 and there is no documentation of contractor's investigation.

OBSERVATION 3

The summary of records for HCT/Ps did not contain an interpretation of results of all communicable disease tests performed.

Specifically, the Summary of Records for CMV positive donors only lists the result as "PASS" and does not also list the result as positive.

A. For example all vials from the following Lot#s: (b) (4), (b) (4), (b) (4), and (b) (4).

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B. The Summary of Records includes Form 001 (Certificate of Analysis) and the Instructions For Use And Product Preparation Guide.

1) Revision 4 of Form 001 removed the test results from the Certificate of Analysis. Revision 4 implemented 6/5/18. From 6/5/18 to present, there were (b) (4) Lots affected.
2) The Instructions for Use And Product Preparation Guide indicates results as "PASS" for all communicable diseases tested and also states "(b) (4) ", which is incorrect for CMV positive donors.

OBSERVATION 4

Release criteria were not verified to have been met through a review of manufacturing and tracking records before HCT/Ps were made available for distribution.

Specifically, there is no assurance product is maintained at appropriate temperatures during transit or upon receipt. The temperature upon receipt from the contract manufacturer is documented as meeting (b) (4) C based on a temperature indicator in the (b) (4) box that is not capable of assuring (b) (4) C.

OBSERVATION 5

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, (b) (4) lots that were tested by an independent party for sterility were released based on preliminary results that showed no growth after (b) (4) ; however, final results of no

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growth at (b) (4) days was received approximately (b) (4) days later (on or about 10/19/17). Following are the lots with vials that were shipped before 10/19/17: (b) (4) [redacted]

OBSERVATION 6

Equipment was not routinely inspected for calibration.

Specifically, there is no proof of calibration for the (b) (4) [redacted] Freezer used to store Regen product.

OBSERVATION 7

Storage temperatures of HCT/Ps were not recorded and maintained.

Specifically, the temperature recordings for the (b) (4) [redacted] Freezer have not been permanently maintained since placed into use on 2/5/18.

OBSERVATION 8

Appropriate shipping conditions were not defined for each type of HCT/P.

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Specifically, the packing configuration used is not supported by the shipping validation. The packing configuration validated includes one vial in the small box with dry ice. However, up to 5 vials can be shipped in the small box. Only one of the three validation runs could be found.

TYH
9/21/18

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