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	5/13/2019-5/23/2019*
	FEI NUMBER 3015381220

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

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

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

Specifically, you have received (b) (4) donors of umbilical cord blood units since January 2019 from your main supplier located in (b) (4) which is an area identified as an active transmission risk area. From the umbilical cord blood units you received, you produced (b) (4) of which (b) (4) vial were further distributed.

A. For example, FDA has identified Zika virus (ZIKV) as a relevant communicable disease agent or disease (RCDAD) under 21 CFR 1271.3(r)(2). Therefore, review of relevant medical records, as defined in 21 CFR *1271.3(s), must indicate that a potential donor is free from risk factors for, or clinical evidence of, ZIKV* infection for the purpose of determining donor eligibility. Form DT-001 "Donor Risk Assessment Interview" utilized by your main supplier of umbilical cord blood located in (b) (4) does not include the full complement of questions required to assess a donor's relevant communicable disease risk as it relates to ZIKV. Form DT-001 only asks donors "Have you ever been diagnosed with or suspected of having dengue, chikungunya or Zika virus." The following questions are missing:

   1. Whether the donor has resided in or traveled to an area with increased risk for Zika virus transmission at any point during pregnancy or
   2. Had sex at any point during pregnancy with a person who has resided in or traveled to an area with increased risk for Zika virus transmission or
   3. Had sex at any point during pregnancy with a person who had a medical diagnosis of ZIKV infection.

B. The firm accepted deficient relevant medical records from their umbilical cord blood supplier that were subsequently used evaluate donor eligibility. Form DT-001 "Donor Risk Assessment Interview" does not

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include complete and/or accurate screening questions related to the following conditions and behaviors that increase a donor's relevant communicable disease risk. For example:

1. Appropriate ZIKV questions as listed above, and
2. Persons who have been diagnosed with vCJD or any other form of CJD.

OBSERVATION 2

HCT/P donors were not determined to be eligible based on the results of donor screening and testing.

Specifically, (b) (4) is identified as an active transmission area for Zika and donors of umbilical cord blood from your main supplier located in (b) (4) (contracted recovery firm) is not properly determining donor eligibility based on donor screening for Zika and CJD risk.

You have received (b) (4) donors of umbilical cord blood units since January 2019 from your main supplier located in (b) (4) which is an area identified as an active transmission risk area. From the umbilical cord blood units you received, you produced (b) (4) of which (b) (4) vial were further distributed.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the aseptic process.

Specifically, since January 16, 2019 to May 21, 2019 your firm processed (b) (4) donations of human umbilical cord blood into (b) (4) vials of biological products of which (b) (4) were distributed, however your firm did not adequately validate the aseptic process used to produce the biological products.

a) You failed to adequately validate your manufacturing process for aseptic controls. For example, your media fill batch sizes are not at least equal to the maximum commercial product batch size made. Your aseptic validation denotes (b) (4) media fills that validated batch sizes of (b) (4) vials, respectively. From (b) (4), you manufactured 17 lots where the lot size ranged from (b) (4) of PURE products.

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Lot Number	Vials Frozen	Vials Released
(b) (6)	(b) (4)	(b) (4)

b) Your firm failed to adequately validate the aseptic process as demonstrated by environmental organisms being detected in product samples as well as environmental monitoring samples. From January 16, 2019 to present, three pre- and post-processing sterility samples that yielded microbial growth with the following identification

Donor Number	Lot Number	Pre Sterility	Post Sterility	Organism ID	Disposition
(b)(6)	(b) (6)	FAIL	PASS	Staphylococcus hominis	Destroyed

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(b)(6)	(b) (6)	FAIL	PASS	Gram positive bacillus	Destroyed
(b)(6)	(b) (6)	FAIL	PASS	Gram positive bacillus	Destroyed

From January 16, 2019 to May 10, 2019, Environmental Monitoring of in process settling plates within the ISO 5 Biological Safety Cabinets (BSC) included growth and identification of Paeniabacillus glucanolyticus on two separate occasions.

Date	Area of failure	Sample type	Organism(s) Id	Number of CFU's	Lot Number	Disposition
1/17/2019	BSC(b) (4) (b) (4)	Air (In Process Settle plate)	Paeniebacillus glucanolyticus	1	(b) (6)	Released
2/20/2019	BSC(b) (4) (b) (4)	Air (In Process Settle plate)	Paeniebacillus glucanolyticus	1	(b) (6)	Released

From February 20, 2019 – May 10, 2019, the Environmental Monitoring sampling of ISO 7(b) (4) gown and clean rooms as well as personnel sampling included the following microbial growths with speciation:

Location/ Sample #	Date Of Sample	Class	Viable Air Level	# of Personnel	Total Microbial Count	Total Count (CFU(b) (4)	Lots Affected	Disposition

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(b) (4) Computer Table (Middle)	2/20/2019	ISO Class 7	Count Below Action Level	3	2 (Staphylococcus hominis)	<2 (no growth)	(b) (6)	**Destroyed Released Released Released
Gowning Room (Center)	2/20/2019	ISO Class (b) (4)	Count Below Action Level	2	2 (Staphylococcus hominis, Bacillus Spp.)	N/a	same lots as above	same lots as above
Gowning Room (Center)	3/6/2019	ISO Class (b) (4)	Count Below Action Level	2	1 (Staphylococcus hominis)	N/a	(b) (6)	Rejected Rejected Rejected Rejected
Door Handle Exterior	3/21/2019	ISO Class (b) (4)	Count Below Action Level	3	1 (Stapylococcus hominis)	1	(b) (6)	Released Released
Gowning Room (Center)	3/27/2019	ISO Class (b) (4)	Count Below Action Level	2	6	6 (Staphylococcus hominis, Bacillus licheniformis)	(b) (6)	Destroyed Destroyed
(b) (6) Upper Torso	4/25/2019	ISO Class 7	N/A	3	Staphylococcus haemolyticus	1	(b) (6)	Released Released Released

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** Lot (b) (6) post-sterility sample and (b) (4) ISO 7 (b) (4) surface samples both identified Staphylococcus hominis.

AMB 5/23/19
AS 5/23/19

c) You failed to conduct sampling according to LL-QA-005 Environmental Monitoring (EM) operating procedure, version 1, effective date 5/14/2019. Section 7.4.4 states (b) (4) (b) (4) shall be performed on a (b) (4) basis in (b) (4) schedule to capture all shifts. From January 18, 2019 – May 20, 2019, the firm failed to conduct (b) (4) EM sampling for a total of 3 weeks.

Dates of missing environmental monitoring sampling	Lots processed	# Vials manufactured And released
(b) (4)	(b) (6)	(b) (4)
(b) (4)	(b) (6)	Total (b) (4) (b) (4)

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	(b) (6)	(b) (4) Total: (b) (4)
(b) (4)	(b) (6)	(b) (4) Total: (b) (4)

e) The raw materials and supplies are labeled for in vitro diagnostic use, or research use and are used in the production of PURE products since production began in January 2019. From January 16, 2019 to May 20, 2019, your firm processed approximately (b) (4) donations of human umbilical cord blood have been processed and approximately (b) (4) vials of biological products were manufactured of which (b) (4) were distributed.

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f) You failed to adequately validate your (b) (4) processing for aseptic controls. For example, Validation of (b) (4) Processing, LL-VAL-005, version 1, effective 01/14/2019, section 1 states that this validation shall define (b) (4) (b) (4) . On 02/26/2019, batch record (b) (6) and (b) (6) were processed (b) (4) by the same operator. You did not validate the processing of two cord blood units by the same operator. Senior laboratory technician and Chief Compliance Officer approximate that (b) (4) processing is being performed (b) (4) of the time.

OBSERVATION 4

Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, You failed to challenge your BSC cleaning described in Validation of Biological Safety Cabinet Cleaning, version 1, effective 5/15/2019, with standard organisms to demonstrate that cleaning and sanitization procedures are effective. Since January 16, 2019 to May 20, 2019, your firm processed approximately (b) (4) donations of human umbilical cord blood have been processed and approximately (b) (4) vials of biological products were manufactured of which (b) (4) were distributed.

OBSERVATION 5

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established, written and followed.

Specifically, the following procedures were not established, written, or followed:

Operating procedure, LL-QA-005 Environmental Monitoring, version 1, effective 05/14/2019, was not established:

a. You failed to establish an appropriate sampling frequency. You are not conducting surface sampling

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per (b) (4) You are currently conducting surface sampling on a (b) (4) basis according to LL-QA-005 Environmental Monitoring operating procedure, version 1, effective 05/14/2019, despite conducting manufacturing on a (b) (4) basis between 1/16/2109 to 5/23/2019.

b. You failed to establish alert and action levels related to microbe or airborne particle levels and appropriate steps to take when alert or action levels are exceeded in your LL-QA-005 Environmental Monitoring, operating procedure, version 1, effective 05/14/2019. Additionally, you have recovered as many as (1) colony in ISO 5, (6) colonies in ISO 7, and (12) colonies in ISO ~~7~~ 8 areas without taking corrective action. AMB 5/23/18 CS 5/23/18

Operating procedure, LL-QA-005 Environmental Monitoring, version 1, effective 05/14/2019, was not followed:

c. According to LL-QA-005 Environmental Monitorin g operating procedure, version 1, effective 05/14/2019, Table 1 – Air Classification, microbiological settling plate action levels for ISO 5 designation is (b) (4) CFU. From 1/15/2019 - 05/10/19, processing settling plates used to assess conformance of ISO 5 yielded 6 growths with 1 CFU's.

d. From 02/09/2019 to 02/13/19, you used (b) (4) contact plate during processing of (b) (4) vials. You failed to validate the use of (b) (4) plates during in-processing. You did validate the use of settle (b) (4) plates in the BSC cleaning validation and aseptic processing validation. You substituted contact (b) (4) plates instead of settle (b) (4) plates due to no inventory of the settle plates. ~~No action was taken by the firm when action levels were met.~~ According to the certificate of analysis, the substituted contact (b) (4) plates do not recovery the organisms. CS 5/23/18 AMB 5/23/18 Slime

Deviation #	Affected lots	# of vials manufactured	Disposition
DV 19-004	(b) (6)	(b) (4)	Shipped
DV 19-005			Shipped Shipped Shipped
DV 19-006			Shipped (b) (4) vials

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DV 19-007	(b) (6)	(b) (4)	Shipped – (b) (4) vials
DV 19-007			Shipped – (b) (4) vials

e. You have not established an aseptic gowning qualification as of 5/21/2019.

f. You began manufacturing on (b) (4) As of 5/13/2019, The following procedures were not reviewed, approved, and implemented:

Operating procedure title	Document No.	Version	Effective Date
Sterility Testing & Investigation of Failures	LL-QA-008	1	none
Product Quarantine & Release	LL-LAB-006	1	none
Validation of Pure Products' Stability	LL-LAB-0069	1	none
Nonconformance	LL-QA-016	1	none

OBSERVATION 6

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

Specifically, You failed to investigate and document 5 of 6 microbial growths of in processing settling plates (EM). While you identified the species on a summary chart, you did not identify a trend of repeating micro-organisms such as Paenibacillus glucanolyticus species.

OBSERVATION 7

A standard operating procedure for the release of HCT/Ps from donors that test reactive for cytomegalovirus (CMV) was not established, maintained, defined and documented.

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Specifically, there is no procedure that describes the current practice of additional or further testing performed for CMV IgG and CMV IgM when the CMV total antibody test is reactive and how to evaluate the further testing results for purposes of donor eligibility and release to the distributor.

OBSERVATION 8

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically, the Product Complaints procedure (LL-Q-015) lacks detailed instructions.

1. The procedure does not provide time frames in which complaints received by the sales force must be forwarded to log the complaint into the complaint system. It does not provide a time frame in which the complaint form must be initiated, a time frame in which a decision to investigate or not be determined, a time frame in which the investigation must be initiated and completed, and a time frame in which the complaint must be closed.
2. The procedure is not reflective of current practice. It instructs customer service/sales receiving complaints to forward the complaint to the QA department for follow up. Current practice is to forward all complaints to the CCO of Liveyon Labs, Inc. to log into the complaint system and then route to QA for follow up.

OBSERVATION 9

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

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Specifically, you failed to determine an appropriate expiration date. Your stability study titled LL-VAL-019 Validation of PURE Product Stability, version 1, has not been reviewed and approved by a responsible person prior to implementation on 11/30/2018 and is ongoing.

On 5/15/2019, I observed final labeling for batch (b) (6) that denotes a 1-yr expiration date. Chief Compliance Officer of Liveyon Labs Inc. stated that the one-year expiry was assigned on or before 01/15/2019 and was assigned without accelerated studies or other provisional data. Since that time, your firm processed approximately (b) (4) donations of human umbilical cord blood have been processed and approximately (b) (4) vials of biological products were manufactured of which (b) (4) were distributed.

***DATES OF INSPECTION**

5/13/2019(Mon), 5/14/2019(Tue), 5/15/2019(Wed), 5/16/2019(Thu), 5/17/2019(Fri), 5/20/2019(Mon), 5/21/2019(Tue), 5/22/2019(Wed), 5/23/2019(Thu)

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