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| 한 성장에 대한 것을 다 가지 않는 것을 통하는 것이 없다. | 92612-2445 | | 3015381220 | |
| (949)608-2 | 608-2900 Fax: (949)608-4417 | | | |
| | VIDUAL TO WHOM REPORT ISSUED | | | |
| Erin M. Sai | irafe, Chief Compliance O | fficer STREET ADDRESS | | |
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| | a, CA 92887-4601 | Biologica | 1 Drug Manufacture | er |
| observation, or ha action with the FD questions, please c | do not represent a final Agency determin ve implemented, or plan to implement, co A representative(s) during the inspection contact FDA at the phone number and add ECTION OF YOUR FIRM WE OBSERVE ION 1 | prrective action in response or submit this information tress above. | e to an observation, you may di | scuss the objection of |
| Donors were n | not screened by a review of rele | evant medical record | Is for risk factors of con | nmunicable |
| disease agents | and diseases. | | | |
| (RCDA CFR 12 ZIKV in Intervie the full relates t | mple, FDA has identified Zika via D) under 21 CFR 1271.3(r)(2). The 71.3(s), must indicate that a potent fection for the purpose of determin w" utilized by your main supplier complement of questions required to ZIKV. Form DT-001 only asks dengue, chikungunya or Zika viru | herefore, review of re nitial donor is free from ning donor eligibility of umbilical cord blo to assess a donor's re donors "Have you eve | levant medical records, as m risk factors for, or clini . Form DT-001 "Donor R od located in ^(b) (4) elevant communicable dis er been diagnosed with or | s defined in 21 <i>cal evidence of,</i> lisk Assessment does not includ ease risk as it |
| at ar | ether the donor has resided in or the point during pregnancy or | | | |
| incre | sex at any point during pregnanc; eased risk for Zika virus transmiss | ion or | | |
| 3. Had | sex at any point during pregnancy | with a person who h | ad a medical diagnosis of | ZIKV infection. |
| | accepted deficient relevant medic ently used evaluate donor eligibili | | | |
| | EMPLOYEE(S) SIGNATURE | | | DATE ISSUED |
| EE REVERSE THIS PAGE | Abby L Mozeke-Baker, Inv Tania Y Hall, Investigat | | P220y I, Mourstee Baker Investigator Bigend By: Abby L, Mozeke-Soker 37 Date Gigenet: 05-23-2019 14:02:28 | 5/23/2019 |
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| Yorba Linda | , CA 92887-4601 | | al Drug Manufactur | er |
| 1. Ap | propriate ZIKV questions as listed | l above, and | | |
| lonor eligibility You have receiv n(b) (4) | n supplier located ir (b) (4) 7 based on donor screening for Zik 7 ved (b) (4) 4 donors of umbilical cord b which is an area identifie received, you produced (b) (4) of y | a and CJD risk. blood units since Ja | smission risk area. From t | n supplier located |
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| b) You | ur firm failed | to adequate | ly validate | the aseptic | process as de | monstrat | ed by enviro | nmental |
| | ur firm failed | · · · · · · · · · · · · · · · · · · · | 2.10 | | | | | |
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| Computer Table (Middle) | 2/20 |)/2019 | ISO Class 7 | Count Below Action Level | 3 | and the second se | iylococcus ninis) | <2 (no growth) | (b) | (6) | **Destroy Release Release |
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| EE REVE F THIS P | | Abby | ee(s)signature y L Moze la Y Hal | | | | itor | | bbty L. Mozake Baker wedgate gran By: Abby L. Miczele-Seker Sele Signed: 05:23-2019 14:02:28 | DATE ISSU 5/23/ | |
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| DISTRICT ADDRESS AND | | | IAN SERVICES | |
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| (100 meters) and a constraint of a constraint of the | VIJUAL TO WHOM REPORT ISSUED | | | |
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| GITY, STATE, ZIP CODE, C | OUNTRY | TYPE ESTABLISHM | | |
| Yorba Linda | a, CA 92887-4601 | Biologic | al Drug Manufactur | er |
| proced (b) (4) shall be | failed to conduct sampling acc ure, version 1, effective date 5/ e performed on a ^(U) (4) basis i | 14/2019. Section 7.4.4 r ^{(D) (4)} schedule t | Environmental Monitoring states ^(b) (4) o capture all shifts. From . | |
| May 20 |), 2019, the firm failed to condu | | ng for a total of 3 weeks. | - |
| | Dates of missing environmen monitoring sampling | tal Lots processed | # Vials manufactured And released | |
| | (b) (4) | (h) | (b) (4) | 1 |
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| SEE REVERSE DF THIS PAGE | EMPLOYEE(S)SIGNATURE Abby L Mozeke-Baker, I Tania Y Hall, Investig | | Adoy L Mozeles Bahar Institution X Date Signal, 05/23-2019 14:3222 | DATE ISSUED 5/23/20 |

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| FIRM NAME | | STREET ADDRESS | | |
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| | , CA 92887-4601 | and the second s | al Drug Manufacture | ۶r |
| the produ | (b) (4) (b) (4) w materials and supplies are laboration of PURE products since pr 2019, your firm processed appro cessed and approximately ^{(b) (4)} ributed. | roduction began in J | Total: ^(b) (4) <u>Total:</u> (b) (4) | v 16, 2019 to |
| E REVERSE THIS PAGE | EMPLOYEE(S)SIGNATURE Abby L Mozeke-Baker, In Tania Y Hall, Investigat | | Abby L. Mozeku-Takier Investigado Sgeod Dy: Abby L. Mozeku-Jaker State Signed: 05-03-0219 14(02/20 | DATE ISSUED 5/23/2019 |
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| | | F HEALTH AND HUMAN SER | VICES | |
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| | Lrafe, Chief Compliance Off | ficer | | |
| FIRM NAME | | STREET ADDRESS | | |
| Liveyon Lab | | | | |
| CITY, STATE, ZIP CODE, CO | DUNTRY 1, CA 92887-4601 | TYPE ESTABLISHMENT INSPEC | men Drug Manufacture | r |
| of (b) (4) shall de (b) (4) (b) (6) process Compli OBSERVATI Equipment and the safety, iden Specifically Cleaning, vo sanitization approximate | efine(b) (4) were processed ^(b) ⁽⁴⁾ sing of two cord blood units by the s iance Officer approximate that (b) (4) | on 1, effective 01/14/20 On 02/26/2019, bate by the same operator. Senior lab are operator. Senior lab processing is bein opriate intervals to pre of the drug product. cleaning described in Va standard organisms to der uary 16, 2019 to May 20, cal cord blood have been | ch record (b) (6) tor. You did not valio poratory technician and g performed ^{(b) (4)} of vent contamination alidation of Biologics monstrate that cleani , 2019, your firm pro | at this validation and date the nd Chief the time. that would alter al Safety Cabinet ng and cessed |
| re not establish pecifically, the Operating proceed stablished: | ON 5 igned to prevent objectionable m hed, written and followed. following procedures were not establ dure, LL-QA-005 Environmental Mo failed to establish an appropriate san failed to establish an appropriate san EMPLOYEE(S) SIGNATURE Abby L Mozeke-Baker, Investigator | blished, written, or follow onitoring, version 1, effe mpling frequency. You a stigator | wed: ctive 05/14/2019, wa | as not |
| | | | 17 | |

| DISTRICT ADDRESS AND 19701 Fair | | | CALTH AND HUMAN RUG ADMINISTRATION | | | |
|---|---|--|---|---|---|--|
| 19/01 Fair | | | D | ATE(S) OF INSPECTION | 01.04 | |
| Travino CA | | | | /13/2019-5/23/2 | 019* | |
| | 92612-2445 900 Fax:(949)60 | 08-4417 | | 015381220 | | |
| NAME AND TITLE OF IND | VIDUAL TO WHOM REPORT ISSUED | 1 | | | | |
| | irafe, Chief Co | ompliance Offic | | | | |
| FIRM NAME | | | STREET ADDRESS 22667 Old | Canal Rd | | |
| CITY, STATE, ZIP CODE, C | P CODE, COUNTRY TYPE ESTABLIS | | TYPE ESTABLISHMENT IN | SHMENT INSPECTED | | |
| Yorba Linda | a, CA 92887-460 | 1 | Biological | Drug Manufactu | irer | |
| b. Yo ap Ma as con Operating proc c. Ac 05/ des | propriate steps to tal onitoring, operating many as (1) colony rrective action. edure, LL-QA-005 1 cording to LL-QA-0 (14/2019, Table 1 – | a alert and action lev ke when alert or act procedure, version in ISO 5, (6) coloni Environmental Mon 005 Environmental 1 Air Classification, r From 1/15/2019 - 05 | vels related to micion levels are exca 1, effective 05/14, es in ISO 7, and (itoring, version 1, Monitorin g opera nicrobiological se 5/10/19, processin | 09 to 5/23/2019. robe or airborne parti eeded in your LL-QA /2019. Additionally, y 12) colonies in ISO-7 8 , effective 05/14/2019 ting procedure, version tiling plate action lev g settling plates used | -005 Environmenta you have recovered areas without takin mus 5/23/18 5/23/18 9, was not followed: on 1, effective rels for ISO 5 | |
| (b) (4 of s con -take | ettle ^{(b) (4)} plates in t tact ^(b) (4) plates inst | validate the use of (b) the BSC cleaning va- ead of settle (b) (4) action levels were a not recovery the org | (4) plates during alidation and asep lates due to no inv met. According to anisms. | in-processing. You d tic processing validat rentory of the settle p the certificate of ana | ion. You substituted lates. No action was | |
| | Deviation # | Affected lots | # of vials | Disposition | | |
| | Deviation # | Affected 1018 | manufactured | | | |
| | DV 19-004 | (h)(6) | (b) (4) | Shipped | | |
| | DV 19-005 | (b) (6) | | Shipped | | |
| | | | | Shipped Shipped | | |
| | DV 19-006 | + . | | Shipped ^{(b) (4)} vials | _ | |
| | DV 19-000 | | | Simpped viais | | |
| | | | | | | |

| DISTRUCT ADDRESS AND 19701 Fair | FOOD | OF HEALTH AND I AND DRUG ADMINIS | | VICES | |
|--|---|---|---|---|--|
| | PHONE NUMBER | | DATE(S) | OF INSPECTION | |
| the second se | | | | 3/2019-5/23/201 | 19* |
| | 92612-2445 | | FEINUM 3015 | 5381220 | |
| (949)608-2 | 900 Fax:(949)608-4417 | | | | |
| | VIDUAL TO WHOM REPORT ISSUED | | | | |
| | irafe, Chief Compliance O | | | | |
| FIRM NAME Liveyon Lak | The The | STREET AD | 01d Can | al Rd | |
| CITY, STATE, ZIP CODE, C | | and the second se | LISHMENT INSPEC | | |
| | a, CA 92887-4601 | | | rug Manufactur | er |
| | | (b) | | China (b) sints | |
| | DV 19-007 (b) (6 | (4) | | Shipped -(b) Shipped - vials | |
| f. You | have not established an aseptic go began manufacturing on(b) (4) ed, approved, and implemented: | | | 5/21/2019. The following proc | cedures were not |
| | 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 | |
| Iready distribute pecifically, Yo EM). While yourganisms such BSERVATION. standard ope | Nonconformance ON 6 are to thoroughly review any un uted. ou failed to investigate and docu ou identified the species on a sur as Paenibacillus glucanolyticus sp | LL-QA-016 explained disc ment 5 of 6 mi nmary chart, yo ecies. of HCT/Ps fro | repancy w crobial gro ou did not om donors | whether or not the owths of in process identify a trend o that test reactive | sing settling plat f repeating micr |
| here is a failu lready distribut pecifically, Yo EM). While yo rganisms such BSERVATION standard ope | Nonconformance ON 6 ure to thoroughly review any un uted. ou failed to investigate and docu ou identified the species on a sur as Paenibacillus glucanolyticus sp ON 7 rating procedure for the release | LL-QA-016 explained disc ment 5 of 6 mi nmary chart, yo ecies. of HCT/Ps fro maintained, dea | repancy w crobial gro ou did not om donors | whether or not the owths of in process identify a trend o that test reactive | f repeating micr for |

| | INT OF HEALTH AND HUMAN SERVICES OOD AND DRUG ADMINISTRATION | |
|---|---|--|
| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION | |
| 19701 Fairchild | 5/13/2019-5/23/2019* | |
| Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417 | FED NUMBER 3015381220 | |
| | | |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Erin M. Sairafe, Chief Compliance | Officer | |
| | Officer STREET ADDRESS | |
| Erin M. Sairafe, Chief Compliance | | |
| Erin M. Sairafe, Chief Compliance | STREET ADDRESS | |

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.

- 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.
- 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.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S)SIGNATURE Abby L Mozeke-Baker, Tania Y Hall, Invest | | Abity L. Mozaka-Baker Investigator Signed By: Abty L. Micraka-ballet X. Data Styne:: 05-23-2019 14:02-28. | DATE ISSUED 5/23/2019 |
|-----------------------------|--|-------------------------|--|--------------------------|
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|---|-----------------------|---|---------------------|
| DISTRICT ADDRESS AND PHONE NUMBER | | DATE(5) OF INSPECTION 5/13/2019-5/23/201 | 0* |
| 19701 Fairchild Irvine, CA 92612-2445 | | FEINUMBER | .9 . |
| (949)608-2900 Fax: (949)608-4417 | | 3015381220 | |
| NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED | | | |
| Erin M. Sairafe, Chief Compliance | Officer | | |
| FITRM NAME | and the second second | STREET ADDRESS | |
| Liveyon Labs Inc | | 22667 Old Canal Rd | |
| Yorba Linda, CA 92887-4601 | | Biological Drug Manufacturer | |
| 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) 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) *Dates of the state | | | |
| | | Abby I, Morelin-Jaker Investigation Signed By: Abby L, Moreke-biker Duais Eignest: 05-23-2018 14:02-20 | 5/23/2019 |
| RM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE | INSPECTIONAL OB | SERVATIONS | PAGE 12 of 12 PAGES |