

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	DATE(S) OF INSPECTION 5/13/2019-5/23/2019*
	FEI NUMBER 3013957857

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

FIRM NAME Liveyon LLC.	STREET ADDRESS 22667 Old Canal Rd
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CITY, STATE, ZIP CODE, COUNTRY Yorba Linda, CA 92887-4601	TYPE ESTABLISHMENT INSPECTED Biological drug own label distributor
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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

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

Specifically, the Handling Adverse Events/Product Recall procedure (QA-002):

1. Does not provide timeframes in which received complaints must be logged and routed for follow up, timeframes in which a decision to investigate or not must be determined, and a timeframe in which the complaint and/or investigation must be concluded.
2. Does not reflect current practices. The procedure does not address who must receive the complaints for logging and routing. All complaints must be received by the CCO of Liveyon LLC for logging and routing.

***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)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Abby L Mozeke-Baker, Investigator Tania Y Hall, Investigator	Abby L. Mozeke-Baker Investigator Signed By: Abby L. Mozeke-baker X _____	DATE ISSUED 5/23/2019