DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	6/10/2026-6/15/2026*
	FEI NUMBER 3012262584

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Colette D. Courtion, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Joylux, Inc.	5628 Airport Way S Ste 210
CITY, STATE, ZIP CODE, COUNTRY Seattle, WA 98108-2777	TYPE ESTABLISHMENT INSPECTED Specification Developer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The medical device(s) label did not have a unique device identifier (UDI) present in easily readable plain-text.

Specifically,

Your firm does not adhere to UDI labeling conditions for identified medical devices under the associated requirement. This includes formulating the process for ensuring each medical device bears the UDI within its labeling, and ensuring each UDI is appropriately registered in the UDI database. When asked about UDI labeling affixed to the class II (b) (4)), which is intended to (b) (4) your firm's Senior Director of International Supply was unable to provide evidence for this requirement.

OBSERVATION 2

Procedures for timely complaint handling have not been adequately documented.

Specifically,

Your firm does not adhere to the requirement that each organization shall process complaints in a timely manner for four out of five complaints reviewed. Pages 4-5 of your firm's Complaint Handling procedure, Doc No. SOP-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brian R Hendricks, Investigator	X Brian R Hendricks Investigator Signed By: BRIAN R. HENDRICKS JR -S Date Signed: 06-15-2026 09:08:05	6/15/2026

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10003, Revision 1, states that "target duration for investigation is (b) (4) for product complaints" in addition to "the complaint owner or designee is responsible for tracking the status of complaint investigation reports and for ensuring there is timely follow-up and completion of complaint files." For example:

a) Complaint case no. CF-9 related to the (b) (4) opened on 04/29/2025 and closed on 06/05/2026. The complaint references irritation upon use of the product.

b) Complaint case no. CF-105 related to the (b) (4) opened on 05/28/2025 and closed on 06/05/2026. The complaint references irritation and burning sensation upon use of the product.

c) Complaint case no. CF-149 related to the (b) (4) opened on 07/09/2025 and closed on 06/05/2026. The complaint references product odor and dispensing issues.

d) Complaint case no. CF-418 related to the (b) (4) opened on 02/24/2026 and closed on 06/05/2026. The complaint references irritation upon use of the product.

Your firm's Chief Executive Officer was unable to provide adequate justification for complaint time lines throughout the referenced complaint processing activities.

***DATES OF INSPECTION**
6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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	Brian R Hendricks, Investigator X Brian R Hendricks Investigator Signed By: BRIAN R. HENDRICKS JR -S Date Signed: 06-15-2026 09:08:05	6/15/2026

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."