DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	4/21/2026-4/29/2026* FEI NUMBER 3004966182

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven M. Shriver, Owner

FIRM NAME	STREET ADDRESS
Eco Lips, Inc.	6000 Huntington Ct Ne
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cedar Rapids, IA 52402-1268	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 I OBSERVED:

QUALITY SYSTEM

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A.)You failed to ensure the effectiveness of your corrective and preventive actions for the following areas:

1.)Recurring documentation and process deviation errors were documented over the past three (3) years, with approximately twenty-two (22) documented events identified as pertaining to documentation issues and batch record deviations, including the following:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis V Hull, Investigator X Travis V Hull Investigator Signed By: 2004017973 Date Signed: 04-29-2026 08:52:01	4/29/2026

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Reference:	Date:	Description:
DEV-98	3/12/2024	(b) (4) added the night before and allowed to sit overnight without mixing — unapproved deviation from validated process; batch subsequently rejected for OOS assay results.
NCP-268	10/3/2024	Incorrect math and inputs recorded on multiple lot addition sheet — not caught by verifying batcher; discovered during final QA review.
NCP-295	10/28/2024	Batchers did not follow adjusted API inputs specified on the API Calculation sheet.
QE-342	3/10/2025	Multiple issues on batch records including incomplete documentation.
QE-346	3/14/2025	Documentation errors — start time and thermometer ID not recorded; missing verification initials in filling steps.
QE-355	3/27/2025	Batcher accidentally added incorrect ingredient to batch — error immediately noticed; batch restarted.
QE-377/NCP-415	4/23/2025	Failed API Assay — (b) (4) not properly dispersed; thick sludge remaining in bottom of kettle; batch rejected.

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Travis V Hull, Investigator

X Travis V Hull
Investigator
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2.)Recurring labeling errors were documented over the past three years, with approximately nine (9) documented identified as pertaining to mislabeling, including but not limited to:

Reference:	Date:	Description:
NCP-35	6/7/2023	Private label approved and applied to product missing an artistic design element from the printer.
NCP-49	6/14/2023	Product (b) (4) labeled with labels intended for product (b) (4) during private label process.
NCP-300	10/31/2024	Multiple errors on in-line label allocation form resulting in mislabeling — required reprocessing to peel and relabel tubes.
NCP-400	3/24/2025	Wrong label nearly applied to wrong product — caught during line clearance before anything was labeled.
QE-352/NCP-401	3/24/2025	Mislabeled product shipped to customer — resulted in Class II Voluntary Recall.
QE-650/NCP-478	2/9/2026	Incorrect API listed on label — resulted in Class III Voluntary Recall.

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For both issues above, you identified human error and a lack of adherence to procedures as your root cause. Despite multiple corrective and preventive actions (including document revisions and re-trainings) being initiated in response to these events, unplanned batch record deviations, Good Documentation Practice (GDP) errors, and labeling errors continued to recur, culminating in two Voluntary Recalls:

(A) A Class II Recall of your (b) (4) lip balm product (lot (b) (4) , exp. (b) (4)) due to using incorrect labels. Your customer returned approximately (b) (4) units out of the (b) (4) labeled units shipped.

(A) A Class III Recall of (b) (4) lip balm product (lot no. (b) (4) , exp. (b) (4)) initiated (b) (4) due to incorrect active pharmaceutical ingredient information on the Drug Facts of the lot's labels (the labels stated "(b) (4) " instead of "(b) (4) "). The recall covered (b) (4) units, with your customer committing to dispose of the (b) (4) units on hand at the time of notification.

Also, your firm's corrective action records do not include documented effectiveness checks with defined measurable criteria with metrics, responsible parties, or timelines, for verifying that corrective actions achieved their intended results. Your firm's Quality Unit failed to provide assurance that the patterns noted above will not recur.

Your procedures EL-QA-SOP-0055 Rev. 03 (eff. 5/9/2025)-- Change Controls, Policy 7.6.2. (for Change Controls and Engineering Change Notifications), and EL-QA-SOP-0054 Rev. 07 (eff. 3/4/2025)-- Quality Events, Policy 7.9.1. (for CAPA actions such as CARs/CAs and PARs) require verification of effectiveness for changes and CAPA actions.

Currently, you have approximately (b) (4) released and shipped lots within expiry under multiple

labels for multiple domestic and foreign customers. You could not confirm the amount of product currently on the U.S. market. For example, (b) (4) Lip Balm product (lot no. (b) (4), exp. (b) (4)), which your firm recalled on (b) (4) due to inaccurate API information on the label. Your firm received (b) (4) lot no. (b) (4) with a retest date of 7/26/2028 (internally known as (b) (4), lot no. (b) (4) - (b) (4)) on [enter receiving date] in interstate commerce. The lot passed testing on or around 3/28/2025, and your quality unit approved the lot's Certificate of Analysis (CoA) on 4/11/2025. You used the above raw material lot in the manufacture of (b) (4) Lip Balm (b) (4) product (lot no. (b) (4) - (b) (4), exp. (b) (4)) on (b) (4) The filled lot passed finished product testing on or around 7/30/2025, and the results received Quality Unit approval on 7/30/2025. The Quality Unit approved the filled lot's Certificate of Analysis (CoA) dated 8/5/2025 on 8/6/2025. On 8/13/2025, your operators used (b) (4) Lip Balm product labels that erroneously stated "(b) (4)" instead of "(b) (4)" in the Drug Facts section to label the filled product lot. Your quality unit released the lot on 8/18/2026 and shipped the product in interstate commerce to the U.S. market on 8/18/2025.

B.)Your SOP EL-QA-SOP-0039 Rev. 05 (eff. 5/8/2024)-- *Vendor, Sub-Contractor, and Contract Laboratory Qualification and Review* does not cover audits of your Active Pharmaceutical Ingredient (API) manufacturers and you have not conducted formal audits and re-evaluations on any of your API manufacturers (which manufacture APIs such as (b) (4), and (b) (4)) in accordance with SOP EL-QA-SOP-0039 Rev. 05 (eff. 5/8/2024)-- *Vendor, Sub-Contractor, and Contract Laboratory Qualification and Review*, Policies 7.8 & 7.9. You did not provide a scientific justification for doing so.

Currently, you have approximately (b) (4) released and shipped lots within expiry under multiple labels for multiple domestic and foreign customers. You could not confirm the amount of product currently on the U.S. market. For example, for your (b) (4) lip balm product (lot no. (b) (4) - (b) (4), exp. (b) (4)), your firm received (b) (4) lot no. (b) (4) (retest date of 7/26/2028; internally known as (b) (4), lot no. (b) (4)) on 8/18/2025 in

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interstate commerce. The lot passed testing on or around 3/28/2025, and your quality unit approved the lot's Certificate of Analysis (CoA) on 4/11/2025.You used the above raw material lot in the manufacture of(b) (4) Lip Balm product (lot no. (b) (4) , exp. (b) (4)) on (b) (4) The lot passed finished product testing, the Quality Unit approved the filled lot's Certificate of Analyses (CoAs) for chemistry testing dated 8/1/2025 on 8/6/2025, and approved the CoA for the microbiological testing dated 8/9/2025 on 8/12/2025. Your quality unit released the lot on 7/23/2025 and shipped the product in interstate commerce to the U.S. market on 8/22/2025.

***DATES OF INSPECTION**

4/21/2026(Tue), 4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed)

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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."