

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 1777 Hardee Ave SW Atlanta, GA 30310 (404) 253-1284 Fax: (404) 669-4443		DATE(S) OF INSPECTION 3/24/2026-3/26/2026 FEI NUMBER 3009878984	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Andy Boutros, President, CEO			
FIRM NAME Cosmetics & Cleaners International LLC		STREET ADDRESS 2103 Brentwood St	
CITY, STATE, ZIP CODE, COUNTRY High Point, NC 27263-1807		TYPE ESTABLISHMENT INSPECTED Contract Manufacture, Over-The-Counter	
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: OBSERVATION 1 Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products and investigations conducted for each drug product. Specifically, Your firm's control procedure, SOP Q-08 "Annual Product Review" (Version #1, Effective date 04/02/2019), and executed Annual Product Reviews for the 2025 review period (January - December 2025) for (b) (4) drug products (b) (4) Spray lots (b) (4) lot (b) (4)) are inadequate because they fail to include a review and assessment of the following: - Complaints filed - Recalls performed - Returned or salvaged drug products - Stability data - Assessment of any failure to meet specifications - Review of significant, unexplained discrepancies			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Christian F Gomez Lugo, Investigator Christian F Gomez Lugo Investigator Signed By: CHRISTIAN F. GOMEZ LUGO-S Date Signed: 03-26-2026 14:50:56 X _____	
		DATE ISSUED 3/26/2026	

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."