DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	3/5/2026-3/10/2026* FEI NUMBER 3011959287

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Heegun (nmi) Kang, Reseach and Developement Chemist Manager

FIRM NAME	STREET ADDRESS
COSMETIC LABORATORY INC	11933 Woodruff Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Downey, CA 90241-5601	Contract 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 WE OBSERVED:
Production System

OBSERVATION 1

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically,

Your firm's process validation documentation for the manufacture of your firm's OTC (b) (4) as well as (b) (4) (b) (4) drug products, contained no evaluation of batch-to-batch variability, no statistical analysis of the results, and no conclusion regarding whether the process was validated.

For example, the process validation protocol contained the complied test results from (b) (4) batch; however, your firm did not establish conclusion form the data, including whether your firm evaluated the variance between the (b) (4) batches to demonstrate the process consistently produces product meeting predetermined specifications.

Facilities and Equipment System

OBSERVATION 2

Records of the calibration checks of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darren S Brown, Investigator Devisree P Mattigiri, Investigator X Darren S Brown Investigator Signed By: 2001647750 Date Signed: 03-10-2026 14:06:50	3/10/2026

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Your firm failed to establish and follow adequate calibration procedures for weighing scales used in compounding and production areas.

Your firm failed to perform (b) (4) calibrations of your firm's weighing scales.
On 03/09/2026, your firm was unable to provide the evidence that your firm's scales (b) (4) (b) (4), and were performed (b) (4) as required by your firm's SOP-034. titled "Calibration of Equipments", revision 2.

Your firm failed to follow your firm's SOP, SOP-034 – titled "Calibration of Equipments" revision 2, Section 4.2, of the SOP states that an outside calibration service company is responsible for (b) (4) calibration of scales. Your firm's records show that your firm performed the calibration, and not an outside calibration service company as required by your firm's SOP-034. Furthermore, your firm does not have individuals qualified to perform scale calibrations.

Additionally, your firm failed to maintain a scale usage log to document which scales are used for specific OTC drug batches.

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

Your firm failed to conduct a performance qualification for your firm's manufacturing equipment which your firm uses to manufacture OTC drug products. Your firm failed to complete a performance qualification for your firm's (b) (4) Filling Machine (Equipment Item (b) (4), (b) (4) Filler (Equipment Item (b) (4) Main Tank (b) (4) equipment (b) (4) Main Tank (b) (4) equipment ID (b) (4)

This manufacturing equipment was used by your firm to manufacture all of the OTC drug products produced by this firm.

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Materials System

OBSERVATION 4

Written procedures are not followed for the approval of components.

Specifically, your firm failed to follow your firm's SOP, SOP-011, "Vendor Qualification," Revision 3.

According to your firm's vendor qualification SOP, your firm is required to send a "Vendor Qualification Questionnaire" to the vendor as well as request a "Technical Data Package" from the vendor.

During our review of your firm's vendor qualification for your firm's supplier (b) (4)) of (b) (4) (b) (4)), we observed that your firm failed to complete the Vendor Qualification Questionnaire as well as the "Technical Data Package" for the active pharmaceutical ingredient (API), (b) (4) used in the manufacture of your firm's OTC drug product (b) (4) .

Quality System

OBSERVATION 5

The quality control unit lacks the responsibility and authority to approve and reject all components.

Specifically,

Your firm uses subpotent raw materials in the manufacture of your firm's OTC drug products.

For the manufacture of (b) (4) , your firm uses…

(b) (4) which is identified as (b) (4) which is a (b) (4) of (b) (4) and (b) (4) ,

(b) (4) , which is a (b) (4) of (b) (4) and (b) (4) (b) (4)

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This firm manufactured and released to the market the following batches of (b) (4): lot (b) (4) (with fill code (b) (4) and expiry (b) (4) and lot (b) (4) (with fill code (b) (4) and expiry (b) (4)).

*DATES OF INSPECTION

3/05/2026(Thu), 3/06/2026(Fri), 3/09/2026(Mon), 3/10/2026(Tue)

X Devisree P Mattigiri
Investigator
Signed By: DEVISREE P. MATTIGIRI -S
Date Signed: 03-10-2026 14:08:24

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Darren S Brown, Investigator
Devisree P Mattigiri, Investigator

X Darren S Brown
Investigator
Signed By: 2001647750
Date Signed: 03-10-2026 14:06:50

DATE ISSUED
3/10/2026

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."