DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/25/2026-4/1/2026* FEI NUMBER 3003763470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Claudio Avila, Vice President - Manufacturing Florence Plant

FIRM NAME	STREET ADDRESS
L'Oreal Usa, Inc.	7080 New Buffington Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Florence, KY 41042-2808	OTC Drug 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:

OBSERVATION 1

Labels and other labeling materials are not stored separately with suitable identification for each different drug product, strength, dosage form or quantity of contents.

Specifically,

Your firm failed to establish adequate controls for printed drug labels. During the walkthrough on 3/26/2026, I observed printed drug labels for "(b)(4)" (lot # (b)(4)) in the (b)(4) general warehouse area. At the time of inspection, your firm had approximately (b)(4) different printed labels and printed tubes for the (b)(4) different OTC drug products and approximately (b)(4) different cosmetic product labels stored in the (b)(4) general warehouse area (designated for raw materials and packaging materials) and in the (b)(4) general warehouse area (designated for tubes and other packaging components). The storage areas in both general warehouses were not segregated nor controlled for such critical components to prevent mix-ups between labels for different products. Access to the label storage area in the warehouse was not limited to authorized personnel.
In addition, your firm also failed to have documented procedures for label management such as responsibilities, storage, issuance, use and reconciliation of the printed labels and tubes.

OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to the holding of rejected components, drug product containers, closures and labeling before disposition.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	WenNing Chan, Investigator X WenNing Chan Investigator Signed By: 2003086020 Date Signed: 04-01-2026 15:31:41	4/1/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/25/2026-4/1/2026* FEI NUMBER 3003763470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Claudio Avila, Vice President - Manufacturing Florence Plant	
FIRM NAME L'Oreal Usa, Inc.	STREET ADDRESS 7080 New Buffington Rd
CITY, STATE, ZIP CODE, COUNTRY Florence, KY 41042-2808	TYPE ESTABLISHMENT INSPECTED OTC Drug Manufacturer

Your firm failed to provide separate or defined areas necessary to prevent contamination or mix-ups of rejected or damaged raw materials. Rejected materials were stored on the same shelves in the same general warehouse area as approved materials without physical separation or defined boundaries. The storage arrangement did not provide adequate control systems to prevent mix-ups between rejected and approved materials. As of 4/1/2026, there were approximately (b)(4) rejected components in the (b)(4) warehouse area. Additionally, approximately (b)(4) rejected printed cosmetic labels were stored on shelves alongside approved drug and cosmetic printed labels in the (b)(4) warehouse area. This practice creates a risk of cross-contamination and mix-ups between rejected and approved materials.

OBSERVATION 3

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

Specifically,

Your firm failed to establish documented procedures pertaining to the quality control unit at the firm. Specifically, during the inspection, you were unable to provide the following written procedures to ensure thorough investigations and proper procedures were followed and to ensure no mix-ups on the (b)(4) different formulas of OTC drug products your firm manufactured.

- ☐ Written procedures describing the roles and responsibilities of the Quality Control Unit, including Quality Assurance and Quality Control functions and responsibilities.
- ☐ Written procedures for the investigations and management of Out-of-Specifications (OOS) results.
- ☐ Written procedures for the control and review of master and executed batch or packaging production records for the different formulas of the OTC drug products.

***DATES OF INSPECTION**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	WenNing Chan, Investigator	X WenNing Chan Investigator Signed By: 2003086020 Date Signed: 04-01-2026 15:31:41	4/1/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	3/25/2026-4/1/2026*
	FEI NUMBER 3003763470

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Claudio Avila, Vice President - Manufacturing Florence Plant

FIRM NAME	STREET ADDRESS
L'Oreal Usa, Inc.	7080 New Buffington Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Florence, KY 41042-2808	OTC Drug Manufacturer

3/25/2026(Wed), 3/26/2026(Thu), 3/27/2026(Fri), 3/30/2026(Mon), 4/01/2026(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
WenNing Chan, Investigator

X WenNing Chan
Investigator
Signed By: 2003086020
Date Signed: 04-01-2026
15:31:41

DATE ISSUED
4/1/2026

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."