DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	3/2/2026-3/5/2026
	FEI NUMBER 3010166780

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Gulten Erdemir, General Manager

FIRM NAME	STREET ADDRESS
Delta Kozmetik Sanayi Ve Ticaret-Selim Yesil	Bolgesi Aydinli Sb Mahallesi, 6 12 Istanbul Endustri Veticaret Serbest
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sokak Tuzla, Istanbul, 34953 Turkey	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

The written stability testing program is not followed.

Specifically, stability samples intended for long-term stability studies are not identified accordingly. For example:

During the inspection of stability sample room intended to store stability samples under long-term storage conditions i.e., 25°C/60%RH, numerous stability samples of (b) (4) (b) (4) were observed. The site initiated long-term (25°C/60%RH; for 36 months) and accelerated (40°C/75%RH; for 6 months) stability studies for this batch in March 2023 as per Stability Protocol KK-P-03-F29.04. It was observed the stability conditions were not identified on many sample labels. For example, if such sample is swapped from long-term stability chamber to the stability chamber intended for accelerated samples; it could not be detected.

It was observed the firm had only one sample in the stability chamber marked for 36-month testing. The stability samples are tested by in-house QC Lab as well as by the third-party contract testing lab. The firm management failed to provide reasonable explanation how one sample can be tested by both laboratories that involves microbial evaluation as well.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Saleem A Akhtar, Investigator, Dedicated Drug Cadre	X Saleem A Akhtar Investigator, Dedicated Drug Cadre Signed By: 2001638440 Date Signed: 03-05-2026 13:58:41	3/5/2026

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Each lot of components and closures was not appropriately identified as to its status in terms of being quarantined, approved or rejected.

Specifically, (b) (4) packing materials, components, and closures are not identified in the warehouse. For example:

1. During the inspection of the Quarantine Area on 3/2/2026, loose and/or unlabeled containers of packing material/components including (b) (4) Bottles for (b) (4), (b) (4) Bottles to pack (b) (4) (b) (4) Bottle Caps, (b) (4), Bottle Cap (b) (4) were observed. The firm's warehouse procedure, "Transportation, Storage, Stock, and Shipment Procedure DE-P.01-R.18" requires all components/packing materials should be stored in appropriately labeled containers.
2. On 3/2/2026, a container of "(b) (4) Caps", lot number (b) (4), material code (b) (4) was observed in the sealed and labelled carton in the warehouse Quarantine Area. However, when the warehouse personnel scanned the container barcode it did not display this lot under quarantine status. Instead, it indicated only one lot (b) (4) of (b) (4) Caps stored at location (b) (4) (a location used to store approved materials/components). The firm failed to trace (b) (4) Caps, lot number (b) (4) in its electronic warehouse management system ERP-QPS.

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