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	4/13/2026-4/17/2026
	FEI NUMBER 3026767012

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joanne Danjoy, Owner

FIRM NAME	STREET ADDRESS
Optimal Solution Labs LLC	28910 Avenue Penn Unit 211
CITY, STATE, ZIP CODE, COUNTRY Valencia, CA 91355-5438	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer of Over the Counter Drugs and Cosmetics

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, your firm's quality failed to prevent the use of materials which are not suitable for the manufacture of OTC drug products. Your firm's quality control unit released to the market a batch of drug product manufactured with (b) (4) .

The following drug product was manufactured with (b) (4) and release to the market by your firm…

(b) (4) (lot # (b) (4)), batch size (b) (4) , manufactured on (b) (4) and released (b) (4) , (b) (4) each (b) (4) of finished units to the market by your firm' quality unit on 3/20/2026.

Materials System

OBSERVATION 2

Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darren S Brown, Investigator X Darren S Brown Investigator Signed By: 2001647750 Date Signed: 04-17-2026 15:09:37	4/17/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/13/2026-4/17/2026
	FEI NUMBER 3026767012

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joanne Danjoy, Owner

FIRM NAME	STREET ADDRESS
Optimal Solution Labs LLC	28910 Avenue Penn Unit 211
CITY, STATE, ZIP CODE, COUNTRY Valencia, CA 91355-5438	TYPE ESTABLISHMENT INSPECTED Contract Manufacturer of Over the Counter Drugs and Cosmetics

Specifically, your firm failed to establish the reliability of the Certificate of Analyses provided by your firm's raw material suppliers. Your firm manufactures OTC drug product containing (b) (4) . Your firm only confirmed the color, odor, appearance and assay for the (b) (4) that your firm receives from your supplier. The certificate of analysis of (b) (4) provided by your firm's raw material supplier tests the (b) (4) for appearance, form, odor, assay, (b) (4) identification, color, (b) (4) .

OBSERVATION 3

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically, your firm failed to conduct an identification test on incoming component (b) (4) . Your firm only performs color, odor, appearance and assay testing on incoming raw materials. Your firm uses (b) (4) as the active pharmaceutical ingredient in all of your firm's (b) (4) products.

Production System

OBSERVATION 4

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Specifically, your firm failed to take in process samples of your firm's production batches to evaluate uniformity of the batch. Your firm only takes (b) (4) of a manufactured batch at the (b) (4) for analysis by your firm's contract lab.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Darren S Brown, Investigator X Darren S Brown Investigator Signed By: 2001647750 Date Signed: 04-17-2026 15:09:37	4/17/2026

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."