DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	5/27/2026-5/27/2026
	FEI NUMBER 3007466320

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Josh Warren, Vice President, Sales

FIRM NAME	STREET ADDRESS
API Solutions Inc.	25309 Friendship Rd
CITY, STATE, ZIP CODE, COUNTRY Daphne, AL 36526-6278	TYPE ESTABLISHMENT INSPECTED Re-labeler

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

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically, neither the (b) (4) square foot warehouse storage area nor the (b) (4) square foot storage room have had temperature mapping studies conducted to identify the hottest and coldest points within each area and to demonstrate that uniform and appropriate temperature conditions are maintained throughout the storage cycle. The drug products stored in these areas have a defined storage condition of (b) (4) °C, with excursions permitted between (b) (4) °C (controlled room temperature). Without temperature mapping, the firm cannot confirm that all storage zones within these areas consistently meet the required temperature range for the duration of product storage.

Furthermore, the firm does not maintain temperature records for these storage areas, precluding any verification that required temperature conditions have been consistently achieved and maintained during the storage period.

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm's Quality Unit failed to detect the absence of required signatures on batch packaging and re-labeling records. Per your firm's procedure 1-1-1, entitled, "Quality Manual" approved September 7, 2022, part M, "It is the responsibility and authority of the Quality Control/Quality Assurance and Document Control Department to ensure that all product production and control records are reviewed and approved to determine compliance with all established, approved written procedures before a batch is released or distributed."

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anastasia M Shields, Investigator X Anastasia M Shields Investigator Signed By: ANASTASIA M. SHIELDS -S Date Signed: 05-27-2026 17:43:23	5/27/2026

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OBSERVATION 3

GMP training is not conducted with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

Specifically, your firm failed to ensure that personnel received (b) (4) Good Manufacturing Practice (GMP) training in accordance with your own established procedures. There was no documented evidence of completing GMP training as required by your procedure, entitled, "Employee Training", SOP 6-2-2.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Anastasia M Shields, Investigator

X Anastasia M Shields
Investigator
Signed By: ANASTASIA M. SHIELDS -S
Date Signed: 05-27-2026 17:43:23

DATE ISSUED
5/27/2026

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."