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	1/5/2026-1/9/2026
	FEI NUMBER 3013696224

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Donald V. Canal, VP of Operations & RA/QA

FIRM NAME	STREET ADDRESS
Kurin, Inc.	10840 Thornmint Rd, Ste 111
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Diego, CA 92131-3924	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Records of complaint investigations do not include required information.

Specifically, your firm did not adequately document the investigation of Medical Device Report (MDR) related complaint records in accordance with 21 CFR 820.198(e) which requires that each manufacturer's complaint files contain sufficient information to facilitate the review of the complaint, including the name of the device, any corrective action taken, and any reply to the complainant. Your complaint procedure, Titled: Complaint Handling, Doc#: SOP-17, Rev: D, Effective date: 3/28/2022, requested to document complaint investigations, including product and contact information (section, 7.1.2 and 7.5).

During review of 11 MDR-related complaint records, the following deficiencies were observed:

Product Information Deficiencies:

• Three records contained incomplete product information: two records lacked any product information including lot numbers, and one record contained product information but was missing lot number documentation.

Contact Information Deficiencies:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Juanj Wu, Investigator	X Juanj Wu Investigator Signed By: 2001334541 Date Signed: 01-09-2026 10:15:48	1/9/2026

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• Two of the 11 records contained incorrect complainant information.

Corrective Action Documentation Deficiencies:
• One record documented that corrective action was needed but failed to document the detailed corrective action that was mentioned and planned in the corresponding MDR.

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Annotations to Observations

Observation 1:

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Juanj Wu, Investigator	X Juanj Wu Investigator Signed By: 2001334541 Date Signed: 01-09-2026 10:15:48	DATE ISSUED 1/9/2026

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."