DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food & Drug Administration District Office 19701 Fairchild Irvine, CA 92612-2445 949-608-2900 Industry Information: www.fda.gov/oc/industry	3/17-3/20/2026
	FEI NUMBER 2020632

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Larry Thomas, Vice President, Quality and Regulatory Affairs

FIRM NAME	STREET ADDRESS
Spectrum Laboratory Products, Inc.	14422 S San Pedro St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Gardena, CA 90248-2027	API Repacker and Relabeler

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) (WE) OBSERVED:

Observation 1

Your quality unit failed to record, review, and approve all appropriate quality-related documents at the time activities are performed.

Specifically,

During my inspection, I reviewed your Laboratory Cleaning Records (QAF877) for all available months in 2025 and 2026. These records are used to document laboratory cleaning activities as required by your SOP QC-W-8.22, Section 5.9, which states: " (b)(4) cleaning activities shall be documented in QAF877, Laboratory Cleaning Record and reviewed (b)(4) by QC Leadership."

I observed the following deficiencies:

a) Missing Records: Laboratory Cleaning Records for January 2025 and February 2025 were not available for review. Your management stated they suspect these records were not completed.

b) Incomplete Documentation: From March 2025 through March 2026, there were numerous instances where cells were marked "N/A [initials] [date]" without adequate explanation. Your management identified these entries as indicating a lack of evidence that cleaning activities occurred.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Matthew R. Clabeaux -S Digitally signed by Matthew R. Clabeaux -S Date: 2026.03.20 10:07:26 -07'00'	Matthew Clabeaux, CSO	3/20/2026

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Observation 2

Your firm failed to properly maintain buildings, facilities, and equipment used in the manufacture of intermediates and APIs in a clean condition, and failed to establish adequate written procedures for cleaning equipment.

Specifically:

a) Laboratory Hood Cleanliness: During my walk through on 3/17/2026 of your laboratory facilities, I observed analytical hoods where testing is performed to be in an unclean condition. The hoods exhibited corrosion, permanent staining, flaking paint, and accumulation of residue and dust.

These hoods are used for reagent preparation and analytical testing of APIs and raw materials. The condition of these hoods presents a potential risk of contamination to materials and test results.

b) Inadequate Cleaning Procedures: Your SOP QC-W-8.22, "Analytical Laboratory Cleaning," does not specify approved cleaning agents or sanitizing agents for use in the laboratory. The selection of appropriate cleaning agents is left to individual chemist discretion. Your quality management stated that (b)(4) and (b)(4) are primarily used to clean all chemicals, but this is not documented in your written procedures.

Add Continuation Page

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		Matthew Clabeaux, CSO	3/20/2026

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Observation 3

Your firm failed to adequately validate written procedures for cleaning and maintenance of equipment, and failed to monitor cleaning procedures at appropriate intervals after validation.

Specifically:

a) Outdated Cleaning Validation: Your last cleaning validation for production areas was performed in 2001, representing a 25-year gap between validations. This validation may not be representative of the current operations, products, equipment, and cleaning procedures in your facility.

b) Incomplete Current Validation: Your firm provided Document Control Number PJ24-005, titled "Packing and Sampling Rooms Cleaning Validation Protocol," with an Effective Date of 10/14/2024. However, your firm was unable to provide the final validation report demonstrating the efficacy of the cleaning procedures, as the validation has not been completed. Analytical data has been collected, but the final report is still being drafted.

c) Lack of Periodic Monitoring: There is no documented evidence that cleaning procedures have been monitored at appropriate intervals following the 2001 validation to ensure these procedures remain effective during routine production operations.

Add Continuation Page

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SEE REVERSE OF THIS PAGE		Matthew Clabeaux, CSO	3/20/2026

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 judgement, 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."