DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	02/08-02/10/23, 02/13, 02/15-02/17/23, 02/21-02/24/23, 03/06, 03/15, 03/24/23
	FEI NUMBER 2246824

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Russell NMI Kneipp, President & Chief Executive Officer

FIRM NAME	STREET ADDRESS
Spectrum Laboratory Products, Inc.	755, 769 and 777 Jersey Avenue
CITY, STATE AND ZIP CODE New Brunswick, NJ 08901	TYPE OF ESTABLISHMENT INSPECTED Repacker/Relabeler

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

There is a failure to conduct repackaging operations under appropriate environmental conditions to avoid contamination and cross-contamination.

Specifically, the packing rooms within Buildings (b)(4) where API and non-API chemicals such as the (b)(4) line are repackaged, have not been maintained or designed appropriately to minimize cross contamination.

a. Within Building (b)(4) the following were observed:

i. There are no diagrams of a HVAC or air handling system for the packing rooms. There are no procedures or records of maintenance/qualification of the HVAC or air handling system.

ii. Packing Room (b)(4) had a narrow ledge along the (b)(4) walls at approximately half the height of the wall. On 2/8/2023, the walls of Packing Room (b)(4) were observed with yellow-colored streaks leading to the floor from a ledge midway on the wall. Cleaning procedure PK-W-8.03 Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs, Effective Date 1/26/2023 only requires cleaning of the walls to be completed on a (b)(4) (b)(4) basis. The Packaging Logbook (PK-CJ #3, 2/1/23 to 2/14/23) demonstrates that as of 2/8/2023 the (b)(4) cleaning occurred on 2/1/23 and (b)(4) cleaning occurred on 2/6/23. There were approximately (b)(4) lots of chemicals repackaged between 2/2/2023 and 2/6/2023 and (b)(4) number of lots repackaged after 2/6/2023. APIs repackaged in these time frames include but are not limited to (b)(4) on 2/8/2023 and (b)(4) on 2/7/2023.

iii. On 3/14/2023, Packing Rooms (b)(4) which were documented as cleaned as per the respective logbooks, were observed with (b)(4) residue on surfaces such as but not limited to table top scales,

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(b)(4) tables, biological safety cabinet, crevices of tables, on the exterior of the fume hoods, the interior of the fume hoods, between the wall and floor molding, and corner of the walls.

b. The Packing Rooms within Building (b)(4) where APIs and (b)(4) products are repackaged were identified by your staff as an ISO 8 control environment and is advertised on your firm's website as such. There are no procedures, qualifications, or monitoring performed to support this area as ISO 8 certified. Additionally, the following were observed on 2/8/2023:

i. The Non-Hazardous Sampling Room had a (b)(4) table used for sampling with a lower shelf that was covered with (b)(4) spots and (b)(4) (b)(4) samples were collected in the room on (b)(4) (b)(4) (b)(4) (b)(4)

ii. Packing room (b)(4) contained (b)(4) (b)(4) tables: a (b)(4) and a larger table with a scale setting on (b)(4) that appeared to have (b)(4) residue streaks.

iii. Packing room (b)(4) contained spackle or caulk like substances on the wall corner to the left of the chemical fume hood and packaging area. The repackaging operations were stopped due to breaks and all packaging buckets were left uncovered.

iv. Packing room (b)(4) had paint peeling on the wall, located above and to the left of the chemical fume hood. In addition, the floor was discolored yellow along the wall.

v. Packing room (b)(4) contained a table with a scale positioned in front of the chemical fume hood. The (b)(4) table had peeling (b)(4) Magnehelic Gauge to show pressure for the room displayed (b)(4) and was settled below in the (b)(4) area.

vi. Packing room (b)(4) had bottles of reagents such as (b)(4) that were found unlabeled with lot numbers or expirations. A (b)(4) bottle had an expiration date of (b)(4).

Observation 2

Cleaning procedures are not validated.

Specifically,

a. Your firm has not validated cleaning procedures to evaluate the effectiveness and suitability of your cleaning

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agents, (b)(4) to disinfect and adequately remove or neutralize highly potent hazardous APIs. There is no cleaning validation or verification protocol describing the equipment to be cleaned, procedures, materials, acceptable cleaning levels, parameters to be monitored and controlled, sampling locations, and trending.

i. The Quality Control Laboratory has been performing cleaning validation sampling without a protocol or analysis of any of the results. Procedure QAT-CLN02, Packing Room Cleaning Check/UV-Vis, Revision 0.3, Effective 5/9/2013, is the only procedure provided for the cleaning validations. This procedure does not include the microbiological sampling and testing that was performed.

b. Your current cleaning procedure PK-W-8.03 entitled, Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs, fails to include in sufficient detail the cleaning time and proper documentation to ensure the cleaning process can reliably, reproducibly, and consistently reduce the residual levels of previously repackaged product to acceptable levels.

c. Your current cleaning procedure document control number PK-W-8.03 belongs to two separate procedures entitled, Packing Room Sanitation, Revision 11, Effective Date 04/21/2021, and Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs, Revision 4, Effective Date 01/26/2023. The current procedure as indicated by your staff is Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs, Effective Date 1/26/2023. This procedure has reduced the frequency of cleaning the packaging room walls from after every packaging operation as described within Packing Room Sanitation, Revision 11 to cleaning the walls on a (b)(4) basis. There is no cleaning validation study to justify the change in cleaning and no risk assessment to determine this change does not increase the risk of cross contamination. Packaging operations in each room can vary on a (b)(4) basis with multiple chemicals (API and non-API) repackaged within a (b)(4) room in both buildings (b)(4).

Observation 3

There is a lack of defined areas or other control systems for activities within the warehouse.

Specifically, your firm does not have a control system over all raw materials, API and non-API, demonstrating each material's status and location and nor does your firm have defined areas within your warehouse.

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Additionally, there is no traceability of materials throughout the various stages of production within your facility.

a. The Oracle inventory system nor the batch router include the actual location of each chemical stored within the (b)(4) building (b)(4) warehouse. On 2/8/2023, the following chemicals were observed with approval stickers and stored on shelves within the (b)(4) Warehouse however no physical location was identified within Oracle.

i. (b)(4) Lot (b)(4)

ii. (b)(4) Lot (b)(4)

b. The (b)(4) Warehouse used to store (b)(4) chemicals such as (b)(4), and APIs does not have designated areas for materials not entered into Oracle, approved or rejected.

i. Areas of the warehouse are labeled as quarantined however approved chemicals or materials not entered as received within Oracle were observed on the shelves. For example, on 2/8/2023, (b)(4) USP Lot (b)(4) was stored on a shelf that is marked as Quarantine however, the material was not entered into Oracle.

ii. Approved chemicals were observed stored in the receiving area of the warehouse. On 2/8/2023, (b)(4) pallets of (b)(4) Lot (b)(4) were observed stored in the receiving area. All the bags but (b)(4) of (b)(4) contained Approved stickers dated 10/25/2022.

iii. Non-API chemicals, (b)(4) Lot (b)(4) were observed on 2/8/2023 stored within the aisles of the warehouse with the incoming receipt documentation still with the chemical containers. These chemicals were not entered within the Oracle system.

iv. Oracle identified (b)(4) Lot (b)(4), (b)(4) as rejected however, this chemical could not readily be located.

c. There are materials that were documented as sampled as per the sampling logbook within the (b)(4) Warehouse Sampling Room. The materials were listed within Oracle as being in status QCLA, indicating it is with the laboratory. The Quality Control Laboratory did not test the materials. However, the materials are no longer in inventory as per your staff and there are no distribution records or destruction records for these lots.

i. (b)(4) USP, (b)(4) Lots (b)(4) were sampled on 9/8/2022, however batch routers do not include any testing results or indicate that the materials were sampled. These lots could not be located within the warehouse.

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Observation 4

Written procedures are not established and followed for investigating critical deviations or the failure of a batch of API to meet specifications. Investigations do not extend to other batches that may have been associated with the specific failure or deviation.

Specifically,
Out of Specification investigations do not contain supporting documents, statements or interviews with analysts or laboratory technicians to support human error, corrective or preventative actions, appropriate root cause analyses, or review for product impact.
Examples include but are not limited to:
• Out of Specification Investigation 2L-020 was initiated on 11/18/2022 for (b)(4) USP (non-API) exceeding the impurity limit of (b)(4) with a result of greater than (b)(4) ppm (spec is less than (b)(4) ppm). The investigation does not contain supporting documents for the lot tested and the email complaint chain, complaint report for the associated complaint, supporting laboratory notebook documentation, explanation of the investigation steps, or the stock-lot check request.
• Out of Specification Investigation 2J-015 was initiated on 7/21/2020 for (b)(4) USP exceeding the limit for Assay with a result of (b)(4) % (spec (b)(4) %- (b)(4) %). This investigation was reviewed during the retrospective review of all OOS investigation however, the investigation was not identified as needing any corrective actions. The investigation does not contain a statement or interview with the analyst to support the root cause conclusion of the cause being an improper weighing technique.
• Out of Specification Investigation 2L-005 was initiated on 2/23/2022 for an improperly calibrated pH meter. The investigation was not further extended to determine if the uncalibrated pH meter was used for other test methods.
• Out of Specification Investigation 2K-021 was initiated on 3/30/2021 for the use of expired (b)(4) in the preparation of HPLC Buffers. The investigation was not further extended to determine whether the expired (b)(4) (b)(4) was used for other test methods. This investigation was reviewed during the retrospective review of all OOS investigation however, the investigation was not identified as needing any corrective actions.
• All Out of Specification investigations conclude without corrective or preventative actions.

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Observation 5

The suitability of all test methods used was not verified under actual conditions of use and documented.

Specifically, microbiological and analytical test methods have not been validated or verified to establish the reliability of the test methods.
a. Your firm states that microbiological testing is being performed as per USP <61> and USP <62> however suitability studies have not been performed. Growth promotion testing using all the microorganisms as described within the USP is not being conducted. Growth promotion testing is currently performed only using (b)(4) (b)(4) Incubation of Total Yeast and Mold test plates is not consistently being performed for (b)(4) In addition, the microbiology laboratory does not have procedures for test methods or documentation of test results.
i. (b)(4) (b)(4) Lot (b)(4), was incubated for Yeast and Mold for (b)(4) (b)(4) released on 11/01/2022.
b. Method Validation has not been performed for the (b)(4) Endotoxin kit that is utilized for all endotoxin testing performed. The instructions included with the kit are not followed in that the incubation of the test samples are not (b)(4) C but rather are placed into an incubator that is normally set to (b)(4) °C but increased for endotoxin testing.
c. Method verification is not being performed for all analytical testing of USP monographs. Procedure QC-W-8.10, Laboratory – General Procedures, Revision 14, Effective 1/25/2023, section 5.1.3 defines the acceptance criteria for method verification of compendial methods as meeting HPLC system suitability requirements.

Observation 6

Laboratory control records do not include complete data derived from all tests conducted to ensure compliance with established specifications and standards, including examinations and assays. (REPEAT OBSERVATION)

Specifically, the Microbiology and Analytical Laboratory notebooks do not include complete records of testing conducted.

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a. The Microbiology Laboratory notebooks for Endotoxin testing only includes the results of the test sample. Sample preparation, observations of the control set, and incubation are not documented within the notebooks.
b. The Microbiology Laboratory notebooks for Total Aerobic Plate Counts and Total Yeast & Mold Counts do not include when the samples have begun incubation, when the test samples are read and who performed the reads. Testing is not contemporaneously documented. Test results are not always documented.
i. Notebook QCCJ1043 documents the testing for Total Aerobic Plate Counts and Total Yeast & Mold Counts of (b)(4), Lot (b)(4) from 6/7/2022 – 6/10/2022 but the printout of when the product was weighed for testing reads 6/6/2022.
ii. There are no test results for Total Aerobic Plate Count and Total Yeast and Mold Counts within Notebook QCCJ1043 for (b)(4) Lot (b)(4) tested on 10/10/2022, however results are documented on the Certificate of Analysis.
c. Analytical Laboratory notebooks do not include descriptions of the dilution factor for sample preparation for GC analysis. The analytical package printed from the GC does not include chromatograms.

Observation 7
All specifications, sampling plans, and test procedures are not scientifically sound and appropriate to ensure that raw materials, intermediates, APIs, and labels and packaging materials conform to established standards of quality and/or purity.

Specifically,
a. Sampling plans for identification testing of incoming lots of (b)(4) USP, (b)(4) USP, and (b)(4) USP do not include all received containers. Examples include but are not limited to:
i. (b)(4) Router Cat# (b)(4) Lot# (b)(4) Date: 01/11/2022 sampled 7 out of (b)(4) containers received.
ii. (b)(4) Router Cat# (b)(4) Lot# (b)(4) Date: 12/02/2021 sampled 9 out of (b)(4) containers received.
b. The endotoxin specification for (b)(4) USP, (b)(4) are not the same as the specification listed on the manufacturer's Certificate of Analysis. Your firm does not have a change control system to document and justify this change in specification.
i. The Spectrum Certificate of Analysis for (b)(4) states the

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endotoxin specification is (b)(4) EU/ml. The manufacturer's Certificate of Analysis, which is stored with the router and reviewed by the Quality Control Laboratory for release, states the endotoxin specification is <(b)(4) EU/ml. (b)(4) Lot (b)(4), is reported on the Spectrum Certificate of Analysis as having a result of (b)(4) EU/ml. This exceeds the manufacturer's specification of <(b)(4) EU/ml.

ii. The Spectrum Certificate of Analysis for (b)(4) USP, (b)(4) states the endotoxin specification is <(b)(4) IU/g. The manufacturer's Certificate of Analysis states the endotoxin specification is MAX(b)(4) IU/g. (b)(4) USP, (b)(4) Lot (b)(4) is reported on the Spectrum Certificate of Analysis as having a result of <(b)(4) IU/g. Laboratory Notebook QCCJ1044 reports the results for Lot (b)(4) as (b)(4) IU/g.This exceeds the manufacturer's specification of Max (b)(4) IU/g.

c. Incubation for Total Yeast and Mold Plate Counts for all testing performed within the Microbiological Laboratory is not performed within an incubator. Test samples are incubated within a fume hood within the Microbiological Laboratory. The temperature of the Microbiological Laboratory is not consistent and at times, when product is being incubated for Total Yeast and Mold Counts, is below and above the required incubation range of (b)(4) °C.

i. (b)(4) Lot (b)(4) and (b)(4) Lot (b)(4) were incubated for Total Yeast and Mold Counts from (b)(4) Temperatures within the Microbiology Laboratory varied and was as high as (b)(4) °F ((b)(4) °C) and as low as (b)(4) °F ((b)(4) °C).

ii. (b)(4) Lot (b)(4) was incubated for Total Yeast and Mold Counts from (b)(4) . Temperatures within the Microbiology Laboratory varied below the required range and was as low as (b)(4) °C).

d. There is a lack of evaluation of FTIR sample and standard spectra obtained during ID testing. Your firm failed to evaluate the effects of poor sample preparation when performing FTIR for sample identification. The spectral peaks obtained are distorted, with intensities that appear saturated and lose resolution, making evaluation of any potential differences between sample and standard spectra difficult to ascertain.

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Observation 8

Failure to conduct stability studies to justify assigned expiration or retest dates of repackaged API products in different types of containers/closures than that used by the API manufacturer. (REPEAT OBSERVATION)

Specifically,
The Stability Program does not include stability testing to support the expiration date listed on the repackaged APIs. The Stability Program was established based on review of the final repackaged container closures versus the original manufacturer's container closure and the theoretical interactions of the API with light, air, moisture, and temperature within the (b)(4) repackaged container closure. The stability evaluation does not include evaluating the interaction or possible interaction between the specific container closure and the API.

Observation 9

There is a failure to make sure that all critical deviations are investigated and resolved.

Specifically,
a. Temperature excursions of refrigerators and freezers within Buildings (b)(4) are not acknowledged or investigated. Procedure QC-W-6.01 entitled, Environmental Monitoring Facilities, states deviations are to be initiated to investigate temperature excursions of material storage areas. Since 2022, there have been over 60 temperature excursions documented by your Dickson 1 monitoring system. There have been no investigations performed for any of these excursions. An example includes but is not limited to the following:
i. The Walk-In Fridge, within Building (b)(4) located on the (b)(4) had a high temperature excursion lasting over 12 days, 7/22/2022 – 8/3/2022, with an average temperature of 61°F (16.11°C). The temperature setting for this refrigerator is 36 – 46°F (2.22 - 7.78°C).
1. (b)(4) USP, Lot (b)(4) (storage requirement (b)(4) °C) and (b)(4) USP, Lot (b)(4) (storage requirement (b)(4) °C) were stored in (b)(4) Walk-In Fridge (b)(4) during the excursion and distributed to customers.

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b. Procedure QC-W-8.12, Rev. 5, Deviation System does not include detailed instructions on each section required in the investigation. Deviations require a risk assessment and there are no parameters or instructions on conducting risk assessments.
c. Initiated deviations do not include supporting documentation or thorough description of the deviation. Deviations are canceled without documented justification. Examples include but are not limited to:
i. Deviation Report 2022NJ005, initiated 3/1/2022 (still open), was created for 24 temperature excursions that occurred in 2021. There have been no corrective actions taken, no product impact assessments and no root cause analysis is provided.
ii. Deviation Report 2022NJ015, initiated 12/2/2022, was created due to multiple notebooks being issued with the same number. This deviation was cancelled on 12/8/2022 with no justification. There was also no supporting documentation placed with the deviation such as the master logbook pages to show distribution of the books and individuals they were issued to. Logbooks QCCJI043 and QCCJI044 were issued twice in error. QCCJI043 was first issued on 2/4/2022 to a Chemist and again on 6/29/2022 to a different Chemist. QCCJI044 was initially issued on 2/25/2022 to a Chemist and then again on 8/1/2022 to a Laboratory Technician.

Observation 10

There is a failure to conduct complaint investigations to determine the cause.

Specifically,
a. Complaints are received and categorized by your firm's Customer Care department located in (b)(4). Between 11/1/2021 to 2/22/2023, overall, your firm has received 5,679 complaints and the Quality Unit has only reviewed 58 complaints. There is no assurance all complaints for APIs are reviewed by the Quality Unit and are fully investigated. Examples include but are not limited to the following complaints that were not reviewed by the Quality Unit.
i. On 11/10/2022, Complaint ID 165616 was received because a customer received (b)(4) instead of (b)(4) USP.
ii. On 11/30/2022, Complaint ID 174052 was received because (b)(4) USP was received without the proper shipping materials to ensure its temperature requirements of refrigeration.

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iii. On 2/8/2023, Complaint ID 204244 was received because the customer received (b)(4) instead of (b)(4) USP.

b. Your firm does not perform trend analysis for all API drug complaints to identify recurrent problems to implement appropriate corrective and preventive actions or conduct an additional investigation. Examples of such complaints include Broken/Missing Seal complaints, all received on 7/20/2022: complaint ID 107630 for (b)(4) USP; complaint ID 107899 for (b)(4) USP; complaint ID 107918 for (b)(4) (b)(4) USP.

c. Investigations into complaints are not thorough by failing to include all aspects of the complaint.

i. Complaint PC58756 for (b)(4) USP was received for discoloration and clumping of the product. The investigation focused entirely on clumping and did not evaluate the effects of discolorations on the product.

Observation 11

The Quality Unit does not review and approve all appropriate quality-related documents.

Specifically,

a. The Quality Unit does not review the entire router of each lot for completeness and accuracy before its distribution. Examples include but are not limited to:

i. The router for (b)(4) USP, Lot (b)(4) includes voided completed pages of packing operations. There is no notation within the router for the reason the packing operation that was carried out was voided. Errors within the router was not identified or corrected. For example, the (b)(4) repackaging of Lot (b)(4) was done in (b)(4) Packing Room #(b)(4) as per the Room logbook, however it was documented in the batch router as (b)(4) Packing Room #(b)(4)

b. The Quality Unit is not reviewing procedures to ensure they are accurate to the actual practice of the respective department, whether procedures are created for all duties being performed, or retiring procedures when new ones are created. Examples include but are not limited to:

i. Procedure, PRO-W-8.05, Router, Effective 11/28/2022, states the Part A of the router is to be printed by the Receiving Inspector. However, this is not performed by the Receiving Inspector. In fact, Part A of the router is printed by Production Personnel.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sayyem Hussain Akbar	SAYYEM H. AKBAR, INVESTIGATOR Barbara Wilimczyk Mann, Compliance Officer	03/24/2023

ii. There are two cleaning procedures for the Packing Rooms under the same document control number PK-W-8.03: Packing Room Sanitation and Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs. Both cleaning procedures do not have the same content and the most recent revisions conflict in terms of the cleaning frequency and cleaning agents used in the Packing Rooms. The revision histories demonstrate both procedures under the same number were being revised in parallel.

1. The current revision for Packing Room Sanitation procedure is 11 effective on 04/21/2021. Revision 10 of this procedure was effective on 1/13/2020.

2. The current revision for Cleaning and Sanitizing of Packing, Sampling, ISO Class 8 & Microbiology Labs is 4 effective on 01/26/2023. However, revision 3 was effective on 9/13/2022, and revision 2 on 1/10/2020.

iii. There are no procedures describing microbiological testing methods. In addition, there are no procedures for issuing notebooks for the microbiological laboratory and the documentation required within the microbiological laboratory notebooks.

c. The Quality Unit is not ensuring established procedures are followed. Examples include but are not limited to:

i. Procedure QC-W-6.01, Environmental Monitoring Facilities, states that temperature monitoring data is to be reviewed on a (b)(4) basis and the Chief Chemist must initial a chart. However, there were no graphs provided demonstrating a review by the Chief Chemist.

Observation 12

Master Production Records do not include detailed production instructions.

Specifically, routers do not include specific instructions on how to set up (b)(4) for those packing operations requiring it. In addition, the routers do not require the documentation of the quantity of sample being collected and what container was used for the sample collection for incoming receipt testing, in-process testing, and for the retain samples.

a. The router for (b)(4) Lot (b)(4) states the starting quantity was (b)(4). The sampling log indicated the lot was sampled; however, no quantity was documented. The Spectrum Packing Slip shows that (b)(4) was sent to the customer despite both Oracle and the sampling logbook indicating that the lot was sampled.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	02/08-02/10/23, 02/13, 02/15-02/17/23, 02/21-02/24/23, 03/06, 03/15, 03/24/23
	FEI NUMBER 2246824

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Russell NMI Kneipp, President & Chief Executive Officer

FIRM NAME	STREET ADDRESS
Spectrum Laboratory Products, Inc.	755, 769 and 777 Jersey Avenue
CITY, STATE AND ZIP CODE New Brunswick, NJ 08901	TYPE OF ESTABLISHMENT INSPECTED Repacker/Relabeler

Observation 13

Batch Production and Control Records are not dated and signed when issued.

Specifically, there are no control procedures to ensure the routers in use are the original issued document. Routers can be reprinted without identification on the document that it was reprinted. Responsibility has not been assigned to any department for the filing and retention management of completed routers for distributed lots.

Observation 14

There is not an adequate number of personnel qualified by appropriate training to perform and supervise the manufacture of APIs.

Specifically, employees are carrying out duties without being provided any training.
a. Employees in all departments are not trained on procedure QC-W-8.12, Rev. 5, Deviation System. Training records for employees in Packaging, Analytical Laboratory and Quality Assurance did not have training records for procedure QC-W-8.12, Rev. 5, Deviation System. The Quality Assurance Specialist is initiating and completing all Deviations.
b. Employees within the Analytical Laboratory and Quality Assurance do not have training on procedure QC-W-8.06, Out of Specification Laboratory Results. The Quality Assurance Specialist has reviewed Out of Specification Reports 2L-020 and 2M-001, and a Chemist completed the investigation section of the Out of Specification Report 2J-026 and 2K-021 without any documentation of receiving training on the procedure.
c. The Laboratory Technician within the Analytical Laboratory is reviewing the microbiology notebooks and performing microbiology testing with no training records on any of the microbiology methods.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Sayyem Hussain Akbar	SAYYEM H. AKBAR, INVESTIGATOR Barbara Wilmoth Moon Compliance Officer	03/24/2023

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."