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	6/17/2024-7/2/2024* FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kyle Y.Flanigan, Chief Executive Officer

FIRM NAME	STREET ADDRESS
US Specialty Formulations LLC	1401 S Albert St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18103-4141	Outsourcing Facility

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

The quality control unit lacks the responsibility and authority to approve and reject all components, drug product containers, closures, in process materials, packaging material, labeling and drug products.

Specifically,

a. You failed to determine the potency of your finished Sarracenia Purpurea 0.17g/ml drug product. You did not perform or conduct testing prior to release of your drug product to verify the strength you claim on your product label of 0.17g/ml. You have released approximately (b) (4) vials of Sarracenia Purpurea 0.17g/ml injection drug product since June 2022.

b. You failed to determine the potency of your finished Sarracenia Purpurea Bulk Distillate. You did not perform or conduct testing prior to release of your drug product to verify the strength you claim on your finished drug product label of 0.17g/ml. You have released approximately (b) (4) lots of the Sarracenia Purpurea Bulk Distillate which had been used in the production and release of approximately (b) (4) vials of Sarracenia Purpurea 0.17g/mL injection drug product since June 2022.

OBSERVATION 2

Laboratory controls do not include determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components used in the manufacture, processing, packing, or holding of drug products.

Specifically,

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	Ucheabuchi C Chudi-Nwankwor, Investigator X Ucheabuchi C Chudi-Nwankwor Investigator Signed By: Ucheabuchi C. Chudi-Nwankwor -S Date Signed: 07-02-2024 23:36:59	7/2/2024

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a. You received (b) (4) Sarracenia Purpurea plant Pitcher Plant lot (b) (4) on 21st June 2021which was used in the production of Sarracenia Purpurea 0.17g/ml injection finished drug product without any data or documentation specifying/identifying the purity of each lot of shipment from your supplier. This lot was used to compound (b) (4) of 10 mL vials of Sarracenia Purpurea 0.17g/ml injection finished drug product, lot (b) (4)

b. The receiving process for Sarracenia Purpurea plant consists of weighing and visual inspection for odor and color, DNA sequencing and genetic identifications. You do not perform testing of incoming Sarracenia Purpurea plant leaves for residual pesticide per USP <561>, microbial testing, elemental impurities, adventitious toxins such as aflatoxins or carcinogenicity. Additionally, you do not test the Sarracenia bulk distillate or the Sarracenia Purpurea 0.17g/ml injection finished drug product for adventitious toxins such as aflatoxins and carcinogenicity.

OBSERVATION 3

The written stability program for drug products does not include reliable, meaningful and specific test methods.

Specifically,

a. Your established testing specification for Sarracenia Purpurea 0.17g/ml injection drug product failed to provide adequate stability data to support the product for conformance to any established specification throughout the life cycle and to support the labeled 12-month expiry date.

b. The test methods used to determine the stability of Sarracenia Purpurea 0.17g/ml finished drug product are not stability indicating in that they are not capable of identifying potential degradants and impurities in the Sarracenia Purpurea Bulk Distillate or the finished drug product,

c. You failed to provide adequate data to support your 12 months retest date for the Bulk Sarracenia

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released drug product. For example, Bulk Lot (b) (4) was produced on (b) (4), and assigned a (b) (4) retest date of 31st May 2024. This bulk lot was used in the compounding of Final drug product Sarracenia Purpurea injection 0.17g/ml lot (b) (4) on 15th February 2024 with an expiration date of 28th February 2025.

d. You store stability samples for Sarracenia Purpurea 0.17g/ml injection finished drug product in a Stability Cabinet located in a (b) (4) of your warehouse (b) (4) You failed to monitor the temperature or humidity of this cabinet. You did not have any data logger placed in the stability cabinet or records for the temperature or humidity of the cabinet.

OBSERVATION 4

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically,

- ☐ You have compounded and released approximately (b)(batches of Sarracenia Purpurea Bulk Distillate and approximately (b) (4) vials of Sarracenia Purpurea 0.17g/ml injection finished drug product to include Lot (b) (4) to the US market since 2022.

- ☐ You do not have test method designed to determine the potency or concentration of an active ingredient and the constituents of your Bulk Sarracenia Distillate and Final drug product Sarracenia Purpurea injection 0.17g/ml prior to release.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

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Specifically,

a. After exiting the ISO 7 room to the ISO 8 room approximately 10 times: touching supplies, cleaning and sanitizing the floor, measuring the air particulates in support ISO 8 rooms, and documenting on the Production Record; Technician (b) (6), (b) (7) failed to don new gloves adequately re-sanitize the same gloves prior to transferring production materials to the ISO 5 Biological Safety Cabinet BSC (b) (4)
For instance, on 06/19/2024, at 11.52am: after exiting the ISO 7 room to the ISO 8 room multiple times, I observed Tech (b) (6), (b) (7) take supplies from ISO 7 stainless steel table and place them directly into the BSC hood. He repeated the transfer of supplies directly to the BSC hood again at 11:54 am. During the transfer of supplies, he only had one sterile glove donned since he entered the ISO 7 room and all throughout the compounding, capping operations for Sarracenia Purpurea 0.17g/ml Injection Lot (b) (4)

b. Per your procedure SOP: QA-0022 Revision 6," Traffic and Gowning Requirements", dated 25 JAN,2023, section 4.4.15, states that 'an additional pair of gloves should be donned by all personnel trafficking material into the BSC (b) (4) ' and Section 4.4.24 states that 'after exiting (b) (4) sanitize gloves if working in (b) (4) or replace sterile gloves if working or trafficking materials into BSC (b) (4) . Technician (b) (6), (b) who was the sealing technician failed to change or adequately sanitize his gloved hand per your procedure.

OBSERVATION 6

Reserve samples from representative sample lots or batches of drug products selected by acceptable statistical procedures are not examined visually at least once a year for evidence of deterioration.

Specifically, you failed to perform and document an annual visual examination of your retain samples of Sarracenia Purpurea 0.17g/ml injection finished drug products for any evidence of deterioration.

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OBSERVATION 7

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically, your visual inspection program for Sarracenia Purpurea 0.17g/ml injection finished drug products failed to include a process whereby critical defects to include particulates observed during 100 % visual inspected of your finished drug products are investigated and the source of the particulates are determined.

For examples during the 100% visual inspection of the following but not limited lots of Sarracenia Purpurea 0.17g/ml injection finished drug products: lots (b) (4) white particles and dark particles were observed in some of the vials which were rejected. You have not conducted investigations to identify these particles or characterized these particulates found in these batches to determine if they are intrinsic, extrinsic or inherent to the product.

*DATES OF INSPECTION

6/17/2024(Mon), 6/18/2024(Tue), 6/19/2024(Wed), 6/20/2024(Thu), 6/21/2024(Fri), 6/26/2024(Wed), 6/28/2024(Fri), 7/02/2024(Tue)

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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."