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 ORAPHARM1_RESPONSES@fda.hhs.gov	3/21/2022-4/26/2022* FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kyle Y. Flanigan, CEO	
FIRM NAME US Specialty Formulations LLC	STREET ADDRESS 1401 S Albert St
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4141	TYPE ESTABLISHMENT INSPECTED 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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure.

Specifically:

1. (b) (4) aseptic vial filling and sealing operations performed within your ISO 5 classified biological safety cabinet BSC-(b) (4) obstruct first pass HEPA filtered air in the critical zones over open vials and open stoppers. During the (b) (4) aseptic filling of 95% Ethanol for Injection, Lot Number: (b) (4) on 04/05/2022 we observed:

   a. The design of your (b) (4) filling equipment, including the flexible tubing and barbed fitting used as a filling nozzle grasped by the technician during operation, causes the filling technician's fingers to obstruct first pass HEPA filtered air when positioned in close proximity (within 5 cm) above open vials as necessary to direct the flow of the drug product into vials.

   b. During the (b) (4) vial sealing operation, performed simultaneously with vial filling within the BSC(b) (4) by a second technician, movement of trays of filled vials from the filling station to the sealing station is directly over the open pouch of vial stoppers thereby obstructing first pass HEPA filtered air over the exposed stoppers.

2. ISO 5 classified areas were not certified under dynamic conditions. Uni-directional airflow was not

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verified under operational conditions in the ISO 5 critical zone of (b) (4) aseptic filling of drug product vials, (b) (4) of drug product vials, and aseptic connections performed in biological safety cabinet BSC-(b) (4) Your airflow pattern study video from 08/26/2021 shows an individual moving a mass (calibration weight) on and off a bench top balance positioned within the BSC-(b) (4) while "smoke" is introduced to visualize the airflow patterns created. You failed to evaluate airflow patterns in BSC(b) (4) under dynamic conditions that include set up of all the equipment and components routinely used in the production of aseptically filled drug products B-Complex + Chromic Chloride 30 mL for injection and Ethanol for Injection 95%. Furthermore, you do not have a written report stating your conclusions from your evaluation and final approval from your quality unit.

OBSERVATION 2

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

Specifically:
During our observation of (b) (4) aseptic filling of 95% Ethanol for Injection, Lot Number: (b) (4) on 04/05/2022 we observed objectionable practices that provide a route for contamination of finished drug product:

1. The filling technician working within the ISO 5 BSC-(b) (4) places the filling tubing and barbed fitting used as a filling nozzle on nonsterile clean room wipes when filling is paused for actions including passing the tray of filled vials to the sealing operator and receiving new trays of vials for filling.

2. The filling technician working within the ISO 5 BSC-(b) (4) receives vials and stoppers in wrapping (b) (4) with (b) (4) and handled in the ISO 7 classified Room (b) (4) by the support technician donned in non-sterile exam gloves.

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a. Your preparation of vial stoppers in (b) (4) pouches does not facilitate aseptic entry into your ISO 5 classified BSC(b) (4). Vial stoppers are held prior to use in (b) (4) (b) (4) pouches on the table located in the ISO 7 classified Room(b) (4) then (b) (4) with sterile (b) (4) by the support technician donned in non-sterile exam gloves and handed to the filling technician working within the ISO 5 BSC-02.

b. Vials are unwrapped to the last layer of wrapping material and handled in the ISO 7 classified Room(b) (4) by the support technician donned in non-sterile exam gloves then rested on the table located in the ISO 7 classified Room(b) (4). The vial wrapping is (b) (4) with sterile (b) (4) by the support technician donned in non-sterile exam gloves and handed to the filling technician working within the ISO 5 BSC-(b) (4) who then unwraps the vials and proceeds with (b) (4) vial filling.

c. The filling technician touched the BSC(b) (4) benchtop during filling. When the technician rotated trays of vials,(b) (6) fingertips contacted the benchtop, and (b) (6) rested (b) (6) wrists on the benchtop during pauses in filling then proceeded to (b) (4) fill vials.

3. Technicians performing operations within the ISO 5 classified BSC(b) (4) do not change their gloves after contacting surfaces of equipment or components outside the ISO 5 zone before returning to operations within the ISO 5 classified BSC(b) (4).

a. The sealing technician handled spray bottles of (b) (4) and bottles of 95% Ethanol (bulk product) outside of BSC-(b) (4) while in sterile garb and then after (b) (4) with sterile (b) (4) (b) (6) returned to capping and sealing vials inside BSC(b) (4) alongside the filling technician without donning new sterile gloves first.

b. While in sterile garb the sealing technician (b) (4) the (b) (4) crimping machine with sterile (b) (4) in the ISO 7 classified Room(b) (4) then passed the machine into BSC(b) (4) and after (b) (4) with sterile (b) (4) proceeded to cap and seal vials inside BSC-(b) (4) alongside the filling technician without donning new sterile gloves first.

c. The sealing technician opened the door from ISO 7 classified Room(b) (4) to ISO 8 classified Room(b) (4) by hand on the door handle to allow the support technician to pass through and

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then after (b) (4) with sterile (b) (4) returned to BSC (b) (4) and proceeded to cap and seal vials alongside the filling technician without donning new sterile gloves first.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically:

1. During our observation of (b) (4) aseptic filling of 95% Ethanol for Injection, Lot Number: (b) (4) on 04/05/2022 we observed that you use nonsterile clean room wipes inside the ISO 5 classified BSC- (b) (4) for purposes to include:
   a. Sanitization of BSC (b) (4) surfaces with sterile (b) (4) before production.
   b. Resting the filling tubing and barbed fitting used as a filling nozzle on nonsterile clean room wipes when filling is paused.
   c. Wiping the (b) (4) while (b) (4) the filling system.

2. Your procedure SOP # PR-0040 Cleaning of Classified Rooms in the (b) (4) Production Area, Effective Date: 09/03/2021 does not allow sufficient disinfectant (b) (4)) contact time to achieve adequate levels of disinfection of the ceiling panels, ceiling grid, light fixtures, and HEPA filter diffusers. The procedure for (b) (4) room cleaning, including for the ISO 7 classified formulation/filling room (b) (4), instructs personnel to spray these surfaces with (b) (4) then "wipe immediately".

This is a repeat citation from the previous FDA 483 list of observations issued on 05/29/2015 and 08/29/2017; and the Warning Letter dated: 09/30/2016.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

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Specifically:
Your surface and airborne viable monitoring program for aseptic filling operations is not designed and conducted to provide meaningful data to support the quality of your drug products intended to be sterile.

1. You have not established scientific justification for the environmental and personnel monitoring action limits set within your ISO 5 environment. Your response to the action level (b) (4) CFU) provided in your procedure SOP # PR-0041 Environmental Monitoring Program, Effective Date: 08/06/2021 and action level (b) (4) CFU) written in the Test Report permits personnel, surface, and air samples from within the critical zone of the ISO 5 classified biological safety cabinet BSC (b) (4) to yield microbial recoveries of 1 CFU (colony forming unit) without investigation. For example:

   a. You did not investigate recovery of 1 CFU *Priestia aryabhattai / megaterium* from the personnel sample of the filling technician's gloved left hand (fingers) following (b) (4) aseptic filling of B-Complex + Chromic Chloride 30 mL for injection, Lot # (b) (4), Expiration Date: 09/30/2022, and the batch was released on 10/26/2021.

   b. You did not investigate recovery of 1 CFU *Bacillus subtilis / mojavensis* from the personnel sample of the filling technician's gloved right hand (fingers) following (b) (4) aseptic filling of Sarracenia Purpurea 0.17 g/ml for injection, Lot # (b) (4), Expiration Date: 02/28/2023, and the batch was released on 09/28/2021.

2. During our observation of manual aseptic filling operations for 95% Ethanol for Injection, Lot Number: (b) (4) on 04/05/2022, we observed that technicians did not collect personnel monitoring samples immediately following the end of filling. Personnel monitoring was not representative of the filling operation since technicians performed the following activities before sampling:

   a. Cleanup from production, (b) (4) with sterile (b) (4) during this time.

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b. Set up of post-batch environmental monitoring devices, (b) (4) repeatedly with sterile (b) (4) during this time.

c. The filling technician and sealing/support technician both donned new sterile gloves before re-entering BSC (b) (4) to collect personnel samples (Fingers and wrists of both hands). Furthermore, (b) (4)) (4) was visible on the sealing technician's hands during sampling.

3. You do not monitor airborne particulates to ISO 5 air classifications in all critical locations throughout manual filling operations for aseptically filled drug products B-Complex + Chromic Chloride 30 mL for injection and Ethanol for Injection 95%.

According to your procedure SOP # PR-0041 Environmental Monitoring Program, Effective Date: 08/06/2021, airborne particulate monitoring of filling operations in the ISO 5 classified biological safety cabinet BSC (b) (4) is conducted "(b) (4)".

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include validation of the sterilization process.

Specifically:

1. An appropriate sterilization load monitor is not included with each drug product load intended for terminal sterilization. Your procedure SOP # EQ-0003 (b) (4) Operation, Effective Date: 06/22/2021 requires use of a (b) (4) for only the (b) (4) in (b) (4) and (b) (4) for terminally sterilized drug products Medroxyprogesterone Acetate 150 mg/ml for injection and Sarracenia Purpurea 0.17 g/ml for injection.

2. You have not adequately validated the (b) (4) in (b) (4) and (b) (4) for load patterns (b) (4)) containing (b) (4) (received (b) (4) and ready to sterilize) and the filling tubing sets used for (b) (4) aseptic filling of drug products B-Complex + Chromic Chloride 30 mL for injection and Ethanol for Injection 95% and terminally sterilized drug products

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Medroxyprogesterone Acetate 150 mg/ml for injection and Sarracenia Purpurea 0.17 g/ml for injection. You have not directly demonstrated sufficient (b) (4) to (b) (4) prepared for vial filling operations and the interior drug product contact surface of filling tubing sets used for (b) (4) aseptic filling of drug products. Your SOP # EQ-0062, EQ-0062 (b) (4) (b) (4) Validation for (b) (4) and SOP # EQ-0053, EQ-0053 (b) (4) Validation for (b) (4) reported that the validation (b) (4) contained items such as wrenches, door closer plates, sockets, chain and pliers, and beam clamps.

3. You do not have a written procedure for preparing (b) (4) for (b) (4) verification. We observed that vials containing (b) (4) ampules had different volumes of (b) (4) and the (b) (4) volume is not specified and controlled during the preparation for (b) (4).

OBSERVATION 6

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically:

1. There were at least two unsealed loose ceiling tiles in the ISO 7 classified formulation/filling room (b) (4) which houses the ISO 5 classified biological safety cabinet BSC (b) (4). One of the dislodged ceiling tiles was observed above and adjacent to the ISO 5 classified biological safety cabinet BSC-(b) (4)

2. There were loose and dislocated prefilters on three out (b) (4) HEPA Filter/Fan units servicing your (b) (4) clean room suite that may affect the air volume and velocity delivered from each unit and change conditions including the air balance certified during the last (b) (4) clean room certification performed on 08/26/2021. The (b) (4) clean room suite includes the ISO 7 classified formulation/filling room (b) (4) and the ISO 5 classified biological safety cabinet BSC (b) (4)

3. There were numerous roof leaks in the facility evidenced by collection pails and drums observed

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positioned beneath leaks in corridors leading to and within the (b) (4) production facility which houses the clean rooms used for all sterile drug production operations. On 04/08/2022 a leak was observed dripping from the ceiling within the (b) (4) production facility adjacent to the cleanroom suite near the corner of ISO 8 classified Room (b) (4) personnel gowning area. Although you have a plan to repair the building roof, you did not take appropriate measures such as augmented cleaning and sanitization and augmented environmental monitoring in the facility designed to control and understand the environmental microbial challenge to your facility caused by intrusion of water from roof leaks.

4. Quarter round molding used to trim the viewing window to ISO 7 classified formulation/filling Room (b) (4) and to cover the floor to wall joints creates small crevices and edges that may challenge adequate cleaning and sanitization.

OBSERVATION 7

Routine calibration of automatic, mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically:
You have not established a calibration program to include calibration of (b) (4) . You were unable to provide any evidence of calibration for the temperature and timing devices on (b) (4) used for sterilization of components including vial stoppers, equipment including filling tubing, and terminal sterilization of Medroxyprogesterone Acetate 150 mg/ml for injection and Sarracenia Purpurea 0.17 g/ml for injection.

OBSERVATION 8

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Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

Specifically, you do not include quality control testing for sterility of your terminally sterilized drug products prior to release and you do not have adequate support for your program of parametric release for terminally sterilized drug products Medroxyprogesterone Acetate 150 mg/ml for injection and Sarracenia Purpurea 0.17 g/ml for injection. An appropriate sterilization load monitor is not included with each drug product load intended for terminal sterilization.

OBSERVATION 9

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically, each lot of aseptically filled drug products B-Complex + Chromic Chloride 30 mL for injection and Ethanol for Injection 95% and terminally sterilized drug products Medroxyprogesterone Acetate 150 mg/ml for injection and Sarracenia Purpurea 0.17 g/ml for injection is not tested for container closure integrity prior to release.

OBSERVATION 10

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically:

1. You did not adequately evaluate products where actionable microbial contamination was recovered in the ISO 5 classified aseptic processing area during sampling associated with aseptic production.

   Your investigation Process Nonconformance No. 39 initiated for over action level (b)(CFU recovered from the bench top surface sample taken in the ISO 5 classified biological safety cabinet BSC- (b) (4)

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and (b)(4) CFU from the gloved left hand (fingers) personnel sample after (b) (4) filling of Ethanol for Injection 95%, Lot # (b) (4), Expiry: 06/30/2023, was not completed and closed out before the batch was released on 02/03/2022 and the investigation remained open. Gram Variable *Paenibacillus xylanexedens* was identified on both samples and *Sphingomonas yabuuchiea* was identified on the bench top surface sample taken in the ISO 5 BSC-(b) (4)

2. Your investigation Process Nonconformance No. 25 initiated for a sitewide power failure from approximately 2015 on 07/06/2021 to about 1530 on 07/07/2021 was inadequate in that you did not evaluate the impact of the loss of clean room air handling systems operation and pressure cascades on environmental conditions in the clean room facilities including the ISO 7 classified formulation/filling room (b) (4) and the ISO 5 classified biological safety cabinet BSC-(b) (4). Additionally, your investigation did not include an evaluation and response designed to re-establish environmental control in the clean rooms before the next production of sterile drug products commenced on 07/12/2021 with filling of Sarracenia Purpurea 0.17 g/ml for injection, 10ml, Lot # (b) (4), Expiry: 01/31/2023 and Sarracenia Purpurea 0.17 g/ml for injection, 50ml, Lot # (b) (4), Expiry: 01/31/2023.

3. CAPA 2021-03 addresses an OOS for potency in Medroxyprogesterone Acetate 150 mg/ml lot (b) (4), EXP 31 JAN 23. Response flow chart (RFC) level 1 and level 2 investigations both obtained repeat OOS results that did not match the original OOS, and the lot was not released. The CAPA indicates that the potency assay method QC-0034 requires "(b) (4)." However, it does not extend the investigation to your other lots of Medroxyprogesterone Acetate 150 mg/ml. It also does not consider the adequacy of potency assay methods for your other drug products or the methods that govern the other release specifications for Medroxyprogesterone Acetate 150 mg/ml (e.g., bacterial endotoxin, sterility).

Medroxyprogesterone process validation protocol 21-02 includes a risk assessment of the most likely failure modes of the production process. It indicates that as a suspension, this product may be

heterogeneous if the medroxyprogesterone is not wetted properly, which could lead to heterogeneous filling or problems in the fill tubing assembly. You did not investigate how a heterogeneous suspension could affect the final drug product uniformity/consistency or whether mixing tests performed in the process validation support that this problem is adequately controlled or prevented.

4. Process nonconformance 24 was opened for the following:
   - Ethanol for Injection 95% lot (b) (4) EXP 31 DEC 22, where visual inspection yielded a 10.8% failure rate due primarily to white fibers in vials; and
   - Ethanol for injection 95% lot (b) (4), EXP 04 AUG 24, yielded a 10% failure rate due primarily to white fibers in vials.

   The acceptable failure rate in Process nonconformance 24 is stated to be (b) (4) %. The vials used to produce both lots were from the same vendor (b) (4)) lot (b) (4). The resolution was to reject the vials from the lot, but you did not determine definitively whether the white fibers were present on incoming vials from the vendor or if the vials could have become contaminated during production. The investigation did not assess whether other product(s) packaged in the same vendor lot of vials may have been affected or generate CAPA to prevent recurrence of this issue.

5. Process nonconformance 27 was opened for Sarracenia purpurea 0.17 g/mL lots (b) (4) ((b) (4)), EXP 30 APR 23 and (b) (4) ((b) (4)), EXP 30 APR 23 for foreign material found on 5 caps used to seal vials. These caps were determined to originate from the same bag from the vendor. The nonconformance states that the contents of the bag had been (b) (4) before production. No root cause is given, but the investigation states that none of the remaining caps were "found to have same foreign material. The foreign material was most likely in the bag and (b) (4) with the caps." This investigation fails to definitively assess the identity and origin of the foreign material, examine other lots of caps from the same vendor or other products in which this implicated lot may have been used, and generate controls/CAPA to prevent recurrence.

OBSERVATION 11

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

Specifically, you do not have test methods designed to determine the potency or concentration of each active ingredient prior to release of Sarracenia Purpurea 0.17 g/ml for injection drug product.

This is a repeat observation from the previous FDA 483 list of observations issued on 07/23/2019.

OBSERVATION 12

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

Specifically:

1. You do not have stability indicating test methods for Sarracenia Purpurea 0.17 g/ml for injection drug product designed to test the product for conformance to any established specifications throughout its lifecycle and support the labeled 18-month expiry dating.

2. The expiration date for Medroxyprogesterone Acetate 150 mg/ml for injection is not based on sound scientific data. The expiration date of 12 months as stated in QC-0074.F1 is based on a stability report for Medroxyprogesterone Acetate 150 mg/ml for injection lot (b) (4) released in September 2017. This stability report monitors (b) (4) vials at time point (b) (4) but only (b) (4) vial at the (b) (4) (b) (4) and (b) (4) month time points. The assay report form QC-0034.F1, which records stability data for the product, contains an assay result for vial (b) (4) but vials (b) (4) and (b) (4) are crossed out or state "N/A". A sample of (b) (4) is not statistically significant enough to form the rationale for establishing a product expiration date. QC-0034.F1 also states, "Concentrations for all vials must be within the specification range" but results are provided for (b) (4). You have instituted release and stability protocols for more recent lots of Medroxyprogesterone Acetate 150 mg/ml for injection, such as (b) (4) released 3 February 2022, that state that (b) (4) vials should be assayed at each time point. However, you did not retrospectively evaluate the expiration date of this product or perform a risk assessment based on your current requirement to test (b) (4) vials at each time point instead of (b) (4).

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US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	3/21/2022-4/26/2022* FEI NUMBER 3010680515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Kyle Y. Flanigan, CEO	
FIRM NAME US Specialty Formulations LLC	STREET ADDRESS 1401 S Albert St
CITY, STATE, ZIP CODE, COUNTRY Allentown, PA 18103-4141	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

No SOP exists to govern sampling for the stability program. The number of vials chosen for stability is lot-specific and specified in the release and stability protocol for each lot, so controls are lacking to ensure that statistically significant sampling is occurring for stability testing on each lot.

This is a repeat citation from the previous FDA 483 list of observations issued on 07/23/2019.

OBSERVATION 13
Established laboratory control mechanisms are not followed.

Specifically:

1. You do not qualify each lot of (b) (4) cartridges before use for Bacterial endotoxin testing (BET) of drug products including B-Complex + Chromic Chloride 30 mL for injection, Ethanol for Injection 95%, Medroxyprogesterone Acetate 150 mg/ml for injection, and Sarracenia Purpurea 0.17 g/ml for injection.

2. Your procedure SOP QC-0092 Chromatography Column Receipt and Handling stipulates that a usage log shall be maintained for the HPLC column. However, no log is currently in use for the column identified as a (b) (4) Serial #(b) (4) used for Sarracenia Purpurea Bulk Distillate and Sarracenia Purpurea 0.17 g/ml for injection drug product HPLC Identity Assay and (b) (4) Potency Assay. While you indicated that a log will be kept for the next HPLC column you acquire, a log should also be kept for the current one to monitor the column throughout its lifecycle and anticipate the need for column maintenance or replacement.

3. You did not validate your (b) (4) test method for holding product (b) (4) over a specified time period for each applicable drug product. You store product (b) (4) under (b) (4) after use and later test them for integrity. Your procedure SOP # QC-0023 (b) (4) Testing of (b) (4), Effective Date: 06/28/2021 instructs QC Technicians "(b) (4) . Additionally, your procedure does not specify any limitations on the (b) (4) storage time allowed for product (b) (4) prior to

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being integrity tested.

OBSERVATION 14

Determinations of conformance to appropriate written specifications for acceptance are deficient in that they are not made for each lot within each shipment of components used in the manufacture, processing, packing or holding of drug products.

Specifically, your firm receives *Sarracenia purpurea* leaves for processing into bulk distillate and final drug product. The only documentation associated with each shipment of (b) (4) is an email from the (b) (4) supplier stating the weight of (b) (4) shipped. When you receive the (b) (4), you weigh them, perform a visual inspection, and send a sample to a contract lab for (b) (4) identification. You do not test the incoming *Sarracenia purpurea* leaves for potential pesticide content. You also do not test your *Sarracenia purpurea* bulk distillate or final drug product for pesticide content.

OBSERVATION 15

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, your procedure SOP # QA-0022 Traffic and Gowning Requirements, Effective Date: 11/08/2021 does not include requirements for personnel gowning to enter the ISO 8 room (b) (4) for preparation of equipment to enter the ISO 7 Room (b) (4) or to prepare process equipment and components for sterilization including aseptic filling tubing sets. On 03/23/2022, during your aseptic simulation for Static Preservation Solution (SPS-1) (b) (4) filling of IV Bags, Lot # (b) (4), we observed personnel outside the clean room in street clothes, except for shoe covers and exam gloves, wipe down bins with wipes and sterile (b) (4) then enter the ISO 8 room without additional gowning and repeat the wipe down. Additionally, we observed that the clean room technician retrieved the bins without performing a final sanitization wipe down of all the nested bins – only the (b) (4) bin surfaces received (b) (4) before entry to the ISO 7 clean room housing the ISO 5 classified BSC (b) (4) where aseptic operations are performed.

AMENDMENT 1

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OBSERVATION 16

The labels of your outsourcing facility's drug products are deficient.

Specifically:

1. The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10). Specifically, the following information is not found on your drug product labels:
   a. The dosage form.

      Examples of your drug product labels that do not contain this information:

      •B-Complex + Chromic Chloride

   b. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient.

      Examples of your drug product labels that do not contain this information:

      □ Sarracenia Purpurea 0.17 g/mL, 10 mL: The inactive ingredients are listed as salts and volatile bases of Sarraceniaceae (99%) and benzyl alcohol in (b) (4) (0.75%) without reference to what salts and bases of Sarraceniaceae are included and at what proportion.

2. Route of administration.

   Examples of drug product containers that do not contain this information:

   □ Sarracenia Purpurea 0.17 g/mL, 10 mL; Medroxyprogesterone Acetate 150 mg/mL;

AMENDMENT 1

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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Allentown, PA 18103-4141	Outsourcing Facility

Ethanol 95%

OBSERVATION 17

Bulk drug substances used by your outsourcing facility to compound drug products are not each manufactured by an establishment that is registered under section 510 as required by section 503B(a)(2)(C).

Specifically, you manufacture Sarracenia Purpurea 0.17 g/ml for injection finished drug product from the bulk drug substance Sarracenia Purpurea Bulk Distillate produced in your facility which is not registered under section 510 of the Act.

***DATES OF INSPECTION**

3/21/2022(Mon), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu), 3/25/2022(Fri), 4/04/2022(Mon), 4/05/2022(Tue), 4/06/2022(Wed), 4/07/2022(Thu), 4/08/2022(Fri), 4/26/2022(Tue)

X Lori M Newman
Investigator
Signed By: 2003217756
Date Signed: 04-26-2022 13:06:19

AMENDMENT 1

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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."