DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313)393-8139	10/13/2020-10/29/2020* FEI NUMBER 3010039017

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Leonard D. Guyer, MD and Owner

FIRM NAME	STREET ADDRESS
Advanced Nutriceuticals, LLC	836 E 86th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Indianapolis, IN 46240-1806	Producer of Sterile Drug Products

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

You performed aseptic processing outside of a certified ISO 5 area.

Specifically,

On 10/20/2020 we observed your dispensary staff (b) (6) with exposed hands, hair, and streetwear fill (b) (4) 1ML syringes using a stock solution containing Testosterone Cypionate w/ Olive Oil, LOT (b) (4) (EXP 11/30/2020) 10 ML vial inside the unclassified Dispensary Area. In addition, an expiry of 11/30/2020 (BUD 40 days) is assigned to these filled syringes. Any employee in the Dispensary Area can fill these stock solutions into syringes without completing any documentation or receiving training.

- *From 08/03/2020 to 09/25/2020, dispensary staff filled and dispensed approximately (b) (4) batches of syringes of Testosterone Cypionate w/ Olive Oil in the Dispensary Area. The expiry dates for the stock solutions were assigned to these filled syringes. Each batch contained between (b) (4) syringes.*
- *From 08/03/2020 to 09/25/2020 dispensary staff filled and dispense approximately (b) (4) batches of syringes of Nandrolone w/ Olive Oil in the Dispensary Area. The expiry dates for the stock solutions were assigned to these filled syringes. Each batch contained between (b) (4) syringes.*

OBSERVATION 2

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	Bei Y He, Investigator Jon P Antoniou, Investigator	X Bei Y He Investigator Signed By 2001878494 Date Signed 10-29-2020 06:31:05	10/29/2020

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The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area).

Specifically,

The ISO 5 IV hood used to produce IV bags is located within the unclassified IV room. This room is an office for your Naturopathy doctor and Phlebotomist (b) (6) There are computers, printers, and two doors leading into this room where the ISO 5 IV hood is located. Your IV room is unclassified. For example, your patient records show that on 09/30/2020 your Naturopathy doctor produced an IV bag using (b) (4) . According to your Naturopathy doctor, this IV bag with (b) (4) additive was produced inside the ISO 5 IV hood in the IV room. An expiration date of "03-Oct-2020" was assigned to this IV bag according to your patient IV therapy records. This IV bag was shipped from your clinic to a patient located in California on 09/30/2020 and arrived on 10/01/2020.

OBSERVATION 3

Your employees touched equipment and other surface areas outside the ISO 5 area with gloved hands and proceeded to aseptically process drug product without changing or sanitizing gloves.

Specifically,

On 10/14/2020 and 10/16/2020, we observed your sterile technician perform aseptic techniques in the ISO 5 Cleanroom hood. Your sterile technician's practice of sanitizing sterile gloved hands and changing of gloves in between contacting non-sterile and sterile materials is inadequate. For example:

A) On 10/16/2020 while aseptically processing Selank 1000MCG/ML 5 ML, LOT 1016202002 EXP 11/16/2020 from non-sterile to sterile in the ISO 5 Cleanroom hood:

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1. We observed your sterile technician touch or retrieve items outside the ISO 5 Cleanroom hood a total of fourteen (14) times. These include touching the staging cart handle bar, retrieving vials from a non-sterile (b) (4) bag outside the ISO 5 area, and retrieving a syringe outside the ISO 5 area. In between retrieving items from outside of the ISO 5 area, we observed your employee sanitize their gloved hands only once.

2. We observed your sterile technician adjusted their face mask in between aseptic (b) (4) with gloved hands in the ISO 5 Cleanroom hood. This employee did not sanitize their gloved hands after touching the face mask.

3. We observed your sterile technician's gloved hands were visually contaminated and wet with (b) (4) drug product while attaching a (b) (4) to a syringe which contained (b) (4) product. After the gloves were contaminated, your sterile technician did not don a new pair of gloves and only sanitized this contaminated glove with sterile (b) (4) before proceeding to aseptically (b) (4) Selank LOT 1016202002 EXP 11/16/2020 from non-sterile to sterile in the ISO 5 Cleanroom hood.

B) On 10/14/2020, we observed your sterile technician grabbing the trash bin located outside the ISO 5 area with their gloved hands. Your sterile technician neither donned a new pair of sterile gloves nor sanitized their gloved hands before returning to admix a Myer's Cocktail IV bag in the ISO 5 Cleanroom hood. Your sterile technician added the following but not limited to Ascorbic Acid LOT (b) (4) EXP 11/20/2020, Potassium Phosphate LOT (b) (4) EXP 11/10/2020, Glutathione LOT (b) (4) EXP 11/18/2020, and B Complex LOT (b) (4) EXP 11/28/2020 into an IV bag in the Cleanroom hood on 10/14/2020.

OBSERVATION 4

Your sterile technician moved rapidly in the vicinity of open sterile units or instruments.

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Specifically,

On 10/16/2020 we observed your sterile technician open a (b) (4) packaging, attach (b) (4) to the syringe, and fill a vial while aseptically processing Selank 1000 MCG/ML 5 ML, LOT 1016202002 EXP 11/16/2020 from non-sterile to sterile. Your technican's movements were not slow and deliberate in this sequence of events, which occurred over the course of approximately 25 seconds.

You produced sterile drug products using non-sterile (b) (4) in the ISO 5 Cleanroom Hood. These products include but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000 MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML.

OBSERVATION 5

Your sterile technician conducted aseptic manipulation and placed equipment/supplies in an area that blocks the movement of first pass air around an open unit.

Specifically,

On 10/16/2020 we observed your sterile technician obstruct the first pass air around the (b) (4) at least eight times while aseptically processing Selank 1000 MCG/ML 5 ML, LOT 1016202002 EXP 11/16/2020 from non-sterile (b) (4) in the ISO 5 Cleanroom hood.

You produced sterile drug products using non-sterile (b) (4) in the ISO 5 Cleanroom Hood through this same (b) (4) stoppering process. These products include but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-

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157 2000 MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML.

OBSERVATION 6

Your sterile technician (b) (4) stoppered sterile drug vials.

Specifically,

On 10/16/2020 after aseptic (b) (4) with a (b) (4), we observed your sterile technician (b) (4) stoppered (b) (4) vials containing Selank 1000 MCG/ML 5 ML vials, LOT 1016202002 EXP 11/16/2020 in the ISO 5 Cleanroom hood. After (b) (4) stoppering, these vials were taken into the Anteroom for crimping and labeling. You did not perform any further sterilization after the drug products were aseptically (b) (4) in the ISO 5 Cleanroom hood.

You produced sterile drug products using non-sterile (b) (4) in the ISO 5 Cleanroom Hood. These products include but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000 MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML.

OBSERVATION 7

Supplies outside of the ISO 5 Cleanroom hood were not disinfected prior to entering the aseptic processing areas.

Specifically,

On 10/14/2020 we observed a bottle of sterile (b) (4) fall onto the floor of the Cleanroom during aseptic processing of IV bags in the ISO 5 Cleanroom hood. The nozzle came into

contact with the ISO 7 Cleanroom floor. Your employee proceeded to pick up the bottle from the ground and use this spray bottle in the ISO 5 area without sanitizing the nozzle.

You produced sterile drug products using non-sterile (b) (4) *in the ISO 5 Cleanroom Hood. These products include but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML. In addition, you produced Myer's Basic IV bags through admixing with sterile ingredients made onsite from bulk to sterile in the ISO 5 Cleanroom hood. This includes for example, Myer's Basic IV bag contains stock solution Ascorbic Acid, Glutathione, B Complex, Potassium Phosphate, B-12, and Sodium Bicarbonate which were made onsite through non-sterile* (b) (4) *by your sterile technician.*

OBSERVATION 8

Systems for monitoring processing and environmental conditions in aseptic processing areas were deficient.
Specifically,

A) Your employees who produced sterile drug products have never performed media fills. For example:

- Your sterile technician who has been producing sterile drug products (from non-sterile to sterile and sterile-to-sterile) for over three years has never performed a media fill during this time.
- Your (b) (4) phlebotomists and Naturopathic Doctor produce IV bags in the IV room, for shipping to out-of-state patients. They have never performed a media fill.

- Your Dispensary staff (b) (6) and Pharmacist fill sterile drug products in the Dispensary room. They have never performed a media fill.

B) Environmental monitoring in the aseptic processing area has not been performed since October 2018. The last time your vendor performed active air sampling in the ISO 5 Cleanroom hood and ISO 5 IV hood was on 10/26/2018. Fungal contamination (1 CFU) was detected in the ISO 5 Cleanroom hood during this sampling. Since then, you have not implemented a program to routinely monitor environmental conditions in the aseptic processing area.

C) Personnel monitoring has never been conducted even though (b) (4) stoppering is (b) (4) performed by your sterile technician when producing sterile drug products from non-sterile to sterile using aseptic (b) (4) For example, on 10/16/2020, we observed your sterile technician (b) (4) stoppered eight vials containing Selank 1000 MCG/ML 5 ML vials, LOT 1016202002 EXP 11/16/2020 in the ISO 5 Cleanroom hood after aseptic (b) (4)

D) (b) (4) testing of the sterilizing (b) (4) were not documented.

You produced sterile drug products using non-sterile (b) (4), these products include but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000 MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML. You produced IV bags from stock solutions which you make through non-sterile (b) (4), these products include but are not limited to IV bag with (b) (4) and Myer's Basic IV bag with Taurine. You filled sterile drug products in syringes, these include Testosterone Cypionate w/ Olive Oil and Nandrolone w/ Olive Oil.

OBSERVATION 9

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Your firm exposed stock solutions, used in the production of drug products intended to be sterile, to worse than ISO 5 quality air.

Specifically,

Stock solutions were stored in an unclassified area for further use after the container closure system had been punctured multiple times, and therefore compromised, throughout the assigned expiry period. For example,

Your sterile compounding log shows that on 09/28/2020, a batch of Testosterone Cypionate w/ Olive Oil stock solution was produced using (b) (4) in the ISO 5 Cleanroom hood and was assigned LOT (b) (4) EXP 11/30/2020.

On 10/20/2020, we observed filling of syringes using of this stock solution LOT (b) (4) EXP 11/30/2020 stored in the unclassified Dispensary room. Prior to filling, we counted at least five (5) existing puncture marks on the vial stopper. The product had been stored at room temperature in an unclassified area for an undocumented period. During filling on 10/20/2020, we observed your dispensary staff (b) (6) puncture this stock solution four times with a syringe needle in an unclassified area and returning this stock solution to a cabinet in the unclassified dispensary room at room temperature for future use. Per your employee, there are no assigned hold time limits for stock solutions that are subject to multiple entries, they go by the expiry date on the stock solution vial.

These include but are not limited to Testosterone Cypionate w/ Olive Oil 10ML stock solutions and Nandrolone w/ Olive Oil 10ML stock solutions produced at your facility using non-sterile (b) (4) .

OBSERVATION 10

The use of sporicidal agents in the aseptic processing area were inadequate.

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Specifically,

your sterile technician did not sanitize the aseptic processing area with disinfectant after maintenance to replace ceiling lights was performed in the ISO 7 Cleanroom on 10/17/2020. Your sterile technician stated that during the morning cleaning on 10/19/2020 the ceiling in the ISO 7 Cleanroom was wiped with sterile (b) (4) only and that disinfectant was not used until the end of the day, after several sterile drug products were made on 10/19/2020.

The following sterile drug products were made on 10/19/2020 through non-sterile (b) (4) in the ISO 5 Cleanroom hood: B12 for IV 2MG/ML, LOT 1019202001 EXP 12/03/2020; B Complex, LOT 1019202002 EXP 12/03/2020; Potassium Phosphate 3MMOL/ML, LOT 1019202003 EXP 12/03/2020; and Hydrogen Peroxide 3%, LOT 1019202004 EXP 11/03/2020.

OBSERVATION 11

The final containers/closures used for drug product intended to be sterile were not sterilized or (b) (4).

A) (b) (4) vials were not appropriately handled and stored to ensure sterility at time of use, specifically, (b) (4) bags are reused for storing sterile vials after the vials are (b) (4). For example, your vials are purchased non-sterile and (b) (4) (b) (4). Your sterile technician stated they wrap vials with (b) (4) before placing it into the (b) (4) and after completing a (b) (4) cycle it is taken into the ISO 5 Cleanroom hood to be aseptically packed into non-sterile (b) (4) bags. According to your sterile technican, the vials are wiped down with sterile (b) (4) and sterile wipes inside the ISO 5 hood before storing in a (b) (4) bag. When asked if the (b) (4) bags are ever reused for storing (b) (4) vials, your sterile technician stated yes.

In addition, unused vials were stored in a non-sterile (b) (4) bag and reused in subsequent batches without further sterilization. For example, after your sterile technician aseptically filled Selank LOT 1016202002 on 10/16/2020, there were four unused opened vials left in the ISO 5 Cleanroom hood. We observed your sterile-technician place these four vials back into a (b) (4) bag containing other (b) (4) vials. Your sterile technician stated that vials that have been (b) (4) and have been brought into the ISO 7 Cleanroom is considered stored regardless of however many times the vials are taken out of the (b) (4) bag.

You produced sterile drug products using non-sterile (b) (4) the ISO 5 Cleanroom Hood. These vials are used on following products but are not limited to: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000MCG/ML, and Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML.

B) **Opened packages of tamper-evident sterile syringe caps are saved and reused in a subsequent batch.** Specifically, on 10/20/2020 we observed your dispensary staff (b) (6) use tamper-evident caps from an existing opened package stored in the unclassified Dispensary Area to fill Testosterone Cypionate w/ Olive Oil LOT (b) (4) EXP 11/30/2020 into from a stock solution into four 1ML syringes.
For example:

- *From 08/03/2020 to 09/25/2020, dispensary staff filled and dispensed approximately (b) (4) batches of Testosterone Cypionate w/ Olive Oil in the Dispensary Area from stock solutions into syringes. The expiry dates for the stock solutions were assigned to these repackaged drug products. Each batch contained (b) (4) syringes for a (b) (4)*

(b) (4) *supplies.*

- *From 08/03/2020 to 09/25/2020 dispensary staff filled and dispensed approximately* (b) (4) *batches of Nandrolone w/ Olive Oil in the Dispensary Area from stock solutions into syringes. The expiry dates for the stock solutions were assigned to these filled drug products. Each batch contained* (b) (4) *syringes for a* (b) (4) *supplies.*

OBSERVATION 12

Your employee produced a sterile drug product using expired material
Specifically,

On 10/16/2020, your Phlebotomist (b) (6) prepare and administer an IV bag containing Taurine, LOT 0827202007 in the ISO 5 IV hood. The Taurine stock solution used to make this lot had expired on 10/12/2020 (four days expired). Your patient records show that this product was administered to a patient on 10/16/2020 at 9:30AM.

Your phlebotomists produced IV bags with additives (e.g., Taurine, (b) (4) *) in the ISO 5 IV hood. These IV bag additives are shipped overnight per patient request.*

OBSERVATION 13

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The ISO-classified aseptic processing areas and surrounding areas had difficult to clean and visibly dirty equipment or surfaces.

Specifically,

During aseptic processing on 10/14/2020 and 10/16/2020, we observed your sterile technician produce Myer's Basic IV Bag (from sterile-to-sterile) and Selank 1000MCG/ML 5 ML, LOT 1016202002 EXP 11/16/2020 (from non-sterile (b) (4)) in the ISO 5 Cleanroom hood. We observed the following:

A) Rust-colored discoloration and damage on all the HEPA filters in the ISO 7 Cleanroom and ISO 8 Anteroom.

B) Rust-colored discoloration on the ISO 5 Cleanroom HEPA filter.

C) ISO 5 Cleanroom workbench is composed of wood-like laminated materials and the top of the workbench is peeling from the side that directly contacts the HEPA filter.

D) A heating vent is located directly underneath the ISO 5 Cleanroom hood and within the ISO 7 Cleanroom. On 10/22/2020, we observed filth build-ups underneath the vent screen and the vent was blowing warm air into the Cleanroom. This air supply vent does not appear to have HEPA filtered air.

E) Your (b) (4) fluid transfer pump with residues and chipped paint on its surface is routinely stored inside the ISO 5 Cleanroom hood during aseptic processing. For example, we observed this equipment in the ISO 5 area during aseptic processing of Myer's Basic IV bag on 10/14/2020 and Selank LOT 1016202002 on 10/16/2020. In addition, we observed this equipment's cord hanging outside the ISO 5 cleanroom hood during aseptic processing. The cord was touching the waste bin and the Cleanroom floor.

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Examples of sterile drug products that you produced inside the ISO 5 Cleanroom hood include:

LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000MCG/ML, Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML, and Myer's Basic IV bag.

OBSERVATION 14

Your facility design allowed the influx of poor-quality air into a higher classified area.

Specifically,

A) ISO 5 IV hood used to produce IV bags is not certified. This hood has not been certified since 10/26/2018 (for over two years).
For example, your patient records show that on 09/30/2020 your Naturopathy doctor produced an IV bag using (b) (4) vial. According to your Naturopathy doctor, this IV bag with (b) (4) additive was produced inside the ISO 5 IV hood in the IV room. An expiration date of "03-Oct-2020" was assigned to this IV bag according to your patient IV therapy records. This IV bag was shipped from your clinic to a patient located in California on 09/30/2020 and arrived on 10/01/2020.

B) You do not have any room pressure monitors installed in the ISO 7 Cleanroom and the ISO 8 anteroom to monitor for potential influx of lower quality air into higher classified areas.
Examples of sterile drug products that you produced inside these rooms include: LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-

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157 2000 MCG/ML, Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML, and Myer's Basic IV bag.

C) ISO 8 Anteroom and ISO 7 Cleanroom are not certified. These rooms have not been certified since 10/26/2018.

Examples of sterile drug products that you produced inside these rooms include: *LL-37 2000MCG/ML, Thymosin Beta 2000MCG/ML, Thymosin Alpha 2000MCG/ML, GHRP 2000MCG/ML, Semax 1000MCG/ML, Selank 1000MCG/ML, Ipamorelin 2000MCG/ML, BPC-157 2000 MCG/ML, Testosterone Cypionate w/ Olive Oil 200MG/ML 10ML, and Myer's Basic IV bag.*

OBSERVATION 15

Beta-lactam and hazardous drugs were produced without providing adequate containment, segregation, and cleaning of work surfaces, utensils, and personnel to prevent cross-contamination.

Specifically,
You produces hazardous drugs in the unclassified Dispensary Area without an adequate segregation and cleaning of equipment and work surface to prevent cross-contamination. The following table includes a list of non-sterile drug products that are produced and sterile drug products that are filled in the unclassified Dispensary Area.

DRUG CLASS	NON-STERILE DRUGS	STERILE DRUGS
Beta-lactam	Ceftriaxone	None

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Hazardous drugs	Anastrozole, Testosterone, Estradiol, Progesterone, Finasteride, Fluconazole, Oxytocin	Testosterone, Nandrolone

For example:

A) On 10/26/2020, we observed your non-sterile technician produce Anastrozole LOT 10-26-2020 B outside of a (b) (4) hood, specifically, your technician was pouring this (b) (4) on a counter near the sink in the unclassified Dispensary room.

B) On 10/22/2020 and 10/26/2020 we observed built-up powder residues on the inside and outside of the capsule counter machine. Per your non-sterile technician, all non-sterile capsule products produced by your firm are counted with this machine. The capsule counter is supposed to be taken apart (b) (4) for deep cleaning and cleaned with (b) (4) (b) (4) prescription order. Your non-sterile technician stated that the capsule counter should have been cleaned (b) (4) batch, but the dispensary staff (b) (6) was too busy with other patient orders. Your non-sterile technician also stated that neither the deep cleaning nor the cleaning (b) (4) (b) (4) is documented.

C) On 10/20/2020 we observed dried white residues on inside of the cleaned blender which is used for mixing (b) (4) non-sterile products. This blender had been cleaned per your non-sterile technician and the blender is cleaned (b) (4).

D) On 10/20/2020 we observed dried white residues on the metal capsule filling tray. We also observed dents and scratches (too numerous to count) on this tray. Your non-sterile technician stated that there are new filling trays in the Dispensary area but they are wait to open this new set of filling trays for when the facility is up to (b) (4).

E) From 10/14/2020 to 10/20/2020 we observed (b) (4) residues built-up behind your (b) (4) non-sterile

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Bei Y He, Investigator Jon P Antoniou, Investigator	X Bei Y He Investigator Signed By 2001878494 Date Signed 10-29-2020 06:31:05	10/29/2020

(b) (4) hoods, on the walls, and windows in the unclassified Dispensary area. According to your non-sterile technician, these non-designated hoods are used for weighing and filling non-sterile drug products. Your non-sterile (b) (4) hoods are cleaned (b) (4) and (b) (4) batches with (b) (4)). Your technician stated that (b) (4) is only used inside these hoods. You do not use any oxidizing or sporicidal agent to decontaminate the (b) (4) hoods after handling these hazardous drug materials. You also do not have any procedures for handling and cleaning hazardous drug products, and you do not document in any way your cleaning activities in these hoods.

F) The dishwasher is used to simultaneously clean equipment used in sterile and non-sterile production, this includes glass beakers and spatulas. Per your non-sterile technician, your firm has not validated that the dishwasher cycle adequately removes residues of hazardous drugs with household detergent ((b) (4)) and does not cause cross-contamination of equipment cleaned in the same cycle.

***DATES OF INSPECTION**

10/13/2020(Tue), 10/14/2020(Wed), 10/15/2020(Thu), 10/16/2020(Fri), 10/19/2020(Mon), 10/20/2020(Tue), 10/22/2020(Thu), 10/26/2020(Mon), 10/27/2020(Tue), 10/29/2020(Thu)

X Jon P Antoniou
Investigator
Signed By: Jon P. Antoniou -S3
Date Signed: 10-29-2020 06:32:04

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."