**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 300 River Place, Suite 5900<br>Detroit, MI 48207<br>(313) 393-8100 Fax:(313)393-8139 | 11/13/2024-11/22/2024*<br>FEI NUMBER<br>3010039017 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Collin M. Baker, Pharmacist

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

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

Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging, and stressful conditions.

Specifically,

The media fill process does not simulate aseptic processing under worst-case conditions. The technicians and pharmacist involved in sterile processing have performed media fills using a (b) (4) (b) (4). This involves aseptically transferring (b) (4) from (b) (4) vial sets into a (b) (4) sterile vial, with (b) (4) vials filled with media for incubation. The current media fill simulates the preparation of a single intravenous (IV) bag; however, technicians produce up to (b) (4) IV bags (b) (4), averaging (b) (4) IV bags per day, with a maximum of (b) (4) IV bags in (b) (4). For example, on 11/13/ 2024, it was observed that technician (b) (6), (b) (7) (C) prepared a total of (b) (4) IV bags (with a BUD of (b) (4)) by mixing up to (b) (4) vials into each IV bag, with (b) (4) IV bags and (b) (4) IV bags prepared (b) (4) in the ISO 5 Laminar Airflow Hood (LAFH).

## OBSERVATION 2

The ISO 5 classified area is located within a non-classified room.

Specifically,

The ISO 5 LAFH, Equipment ID 132224, used for mixing sterile vials into IV bags for infusion, is located within an unclassified room. The most recent (b) (4) certification of the ISO 5 LAFH,

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
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| | Taichun Qin, Investigator<br>X Taichun Qin Investigator Signed By: 2001324646 Date Signed: 11-22-2024 08:32:42 | 11/22/2024 |

dated 6/4/2024, did not include a classification of the IV room. Your firm has been using this IV room since 04/2021.

**OBSERVATION 3**

Vermin or other animals or evidence of their presence was observed in the areas adjacent to production areas.

Specifically,

On 11/13/2024, during the compounding of Estradiol (Lot# 11-13-2024L, 600 capsules, BUD: 5/12/2025), the following observations were made:

A. Dead Insects in Biological Safety Cabinets (BSCs): Dead mosquitoes and other unidentified insects were observed on the isolated top layer of (b) (4) Biological Safety Cabinets (BSCs), Equipment IDs (b) (4) where exhausted air passes through. Although these insects were not in the direct product processing area, their presence on the BSC exhaust layer indicates that contaminants may have ever entered the processing area, which maintains negative pressure relative to the surrounding environment and then exhausted. It remains unclear when and how these insects entered the BSCs, which are located in a segregated and enclosed suite. The firm has been compounding hazardous drugs in this newly constructed hazardous facility since 04/2023, producing approximately (b) (4) batches per day.

B. Live Spider in Non-Sterile Compounding Room: A live spider was observed in the non-sterile hazardous drug compounding room. It was located in a corner on the floor beneath a cart holding two mixers, in a hard-to-reach area.

**OBSERVATION 4**

Use of a sporicidal agent in the facility's was infrequent.

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Specifically,

Your firm uses a sporicidal agent to clean the ISO 5 LAFH (b) (4) . For example, on 11/13/2024, after completing the mixing of (b) (4) IV batches, it was observed a technician cleaning the ISO 5 LAFH using a wiper with (b) (4) , without using a sporicidal agent.

Your environmental sampling report, dated June 11, 2024, identified fungal growth in the surface sample and mold growth in the air sample within the IV room.

**OBSERVATION 5**
Contamination was observed in your production area and areas adjacent to production areas.

Specifically,

A. On 11/13/2024, yellow stain spots were observed inside the HEPA filter of the ISO 5 LAFH after the hood had been cleaned.

B. On 11/13/2024, a cart located next to the ISO 5 LAFH, used for supply storage, was observed to be visibly dirty after cleaning was completed. On 11/14/2024, the cart remained dirty while technician (b) (6), (b) (7) (C) prepared (b) (4) IV bags in the ISO 5 LAFH.

**OBSERVATION 6**
Lack of disinfection of supplies at each transition from areas of lower quality air to areas of higher quality air.

Specifically,

On 11/14/2024, during the mixing of (b) (4) IV bags intended for infusion, it was observed technician (b) (6), (b) (7) (C) failed to disinfect supplies, including syringes and needles, placed in an unclassified area before being

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introduced into the ISO 5 LAFH.

**OBSERVATION 7**

Personnel were observed moving quickly in a critical area or in an area immediately adjacent to a critical area likely causing disruption of unidirectional airflow.

Specifically,

On 11/13/2024, during the mixing of (b) (4) IV bags, the operator was observed moving rapidly while performing the following actions: removing non-disinfected syringes and needles, puncturing vials, inverting vials to draw sterile solutions, and removing needles from syringes. Technician (b) (6), (b) (7) (C) was wearing a gown that left the neck and face exposed in the unclassified IV room.

**OBSERVATION 8**

Use of non-sterile cleaning pads and cleaning wipes in the ISO 5 area.

Specifically,

On 11/14/2023, it was observed that technician (b) (6), (b) (7) (C) used a wiper presaturated with (b) (4) to disinfect vials before introducing them into the ISO LAFH. These vials were subsequently used in the preparation of (b) (4) IV bags. The wiper package did not bear the designation "sterile", and Your firm was unable to provide documentation to verify its sterility. Additionally, your firm could not provide documentation to verify the sterility of the mop wipers used by the technician to clean the ISO 5 LAFH after completing the mixing of these IV bags.

**OBSERVATION 9**

Production areas have difficult to clean or contain porous, particle generating, or visibly dirty equipment or surfaces.

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Specifically,

A. On 11/14/2024, it was observed technician (b) (6), (b) (7) (C) did not conduct thorough cleaning, particularly on the grill of the HEPA filter, the interior surfaces of the front shield, devices installed inside the ISO 5 LAFH, such as the (b) (4) and outlet, after IV bag mixing was completed.

B. Unknown powders were observed on the wheels of the balance and along the edge of the BSC hood after the compounding of Estradiol (Lot# 11-13-2024L, 600 capsules, BUD: 5/12/2025) and the completion of hood cleaning.

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**OBSERVATION 10**

Materials were exposed to lower than ISO 5 quality air.

Specifically,

On 11/13/2024 and 11/14/2024, sterile wipes were observed left open in an unclassified area on a cart near the ISO 5 LAFH. Pharmacist (b) (6), (b) (7)(C) stated that these wipes would be used to clean the ISO 5 LAFH if mop wipers were unavailable.

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***DATES OF INSPECTION**

11/13/2024(Wed), 11/14/2024(Thu), 11/15/2024(Fri), 11/18/2024(Mon), 11/19/2024(Tue), 11/20/2024(Wed), 11/21/2024(Thu), 11/22/2024(Fri)

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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."