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

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 11/28/2022-12/9/2022*<br>FEI NUMBER<br>3011888866 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Sean M. Barclay, Owner and Pharmacist-in-Charge

| FIRM NAME | STREET ADDRESS |
|---|---|
| Barclay, Luke, & Pillai Specialty Pharmacy, PLLC | 8352 W Warm Springs Rd, Suite 120 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Las Vegas, NV 89113-3629 | Producer of Sterile and Non-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 I OBSERVED:**

## OBSERVATION 1

The ISO 5 classified aseptic processing areas had difficult to clean and visibly dirty equipment or surface.

Specifically,

The ISO 5 hoods in your sterile non-hazardous cleanroom, both of which are used to produce drug products purported to be sterile, were observed to contain visibly dirty surfaces during multiple walkthroughs between 11/28/22 and 12/02/22. Those observations include, but are not limited to the following:

a) An accumulation of a fibrous material around the edges of the holes along the work surface front edge, work surface back edge, and side walls of the (b) (4) hood.

b) A paper equipment ID sticker stuck to the left wall of the ISO 5 workspace inside the (b) (4) (b) (4) hood, with visible discoloration underneath the tape covering the sticker.

c) Seven red-brown apparent splatter marks on the surface of the (b) (4) HEPA filter inside the back wall of the ISO 5 (b) (4) laminar flow hood (LFH).

d) An approximate 8" vertical crack in the right side of the plastic sash of the (b) (4) hood.

On 11/29/22, the (b) (4) hood was observed to be used in the production of 100 mL of Niacinamide 100 mg/mL injectable solution, lot 112922JF@(b) (4).

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| | Christopher R Czajka, Investigator | X Christopher R Czajka Investigator Signed By: Christopher R. Czajka -S Date Signed: 12-09-2022 13:07:37 | 12/9/2022 |

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## OBSERVATION 2

Non-microbial contamination was observed in your production area.

Specifically,

Your sterile non-hazardous and sterile hazardous cleanrooms, both of which are used to produce drug products purported to be sterile, were observed to contain several difficult to clean, particle generating, or visibly dirty surfaces during multiple walkthroughs between 11/28/22 and 12/02/22. Those observations include, but are not limited to the following:

a) Apparent rust on multiple metal surfaces in the sterile non-hazardous cleanroom, including wheel casters supporting the (b) (4) °C refrigerator in the southwest corner of the room, wheel casters on a metal cart supporting a (b) (4) positioned adjacent to the (b) (4) °C refrigerator, metal hinges on a (b) (4), and a bolt in the right side of the (b) (4) hood outer casing.

b) Apparent rust on multiple metal surfaces in the sterile hazardous cleanroom, including the metal tabletop used to support the (b) (4) machine, the metal support legs of the (b) (4) (b) (4) biosafety cabinet (BSC), screwheads inside the (b) (4) leading to the non-sterile hazardous cleanroom, the top of the right rear BSC support leg, and the feet on a metal stool positioned under the BSC.

c) Uncovered sprinkler heads in the ceilings of both the sterile non-hazardous and sterile hazardous cleanrooms.

d) Unsealed tiles in the ceilings of both the sterile non-hazardous and sterile hazardous cleanrooms.

e) Apparent cleaning chemical residue on multiple window walls in both the sterile non-hazardous and sterile hazardous cleanrooms, as well as on the hood sashes of the BSC in the sterile hazardous cleanroom and the (b) (4) hood in the sterile non-hazardous cleanroom.

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f) An instruction sheet titled "(b) (4) Processes and Procedures for Utilizing Clean Hoods" taped along all four sides to the (b) (4) hood in the sterile non-hazardous cleanroom with several raised and bubbled areas along each side of the tape.

g) Black tape applied along all four edges of a window between the sterile hazardous cleanroom and the unclassified area in its frame, with the adhesive exposed along all four edges inside the sterile hazardous cleanroom.

h) A metal exhaust pipe installed between the outlet of the BSC and the ceiling of the sterile hazardous cleanroom with raised and bubbled foil tape wrapped around the outside.

i) Sections of damaged wall and gouged floor in the southwestern corner of the sterile non-hazardous cleanroom.

j) An approximate 6" crack along the west edge of a light box cover in the ceiling of the sterile hazardous cleanroom.

k) Three consumer-grade air filters with exposed fabric and cardboard installed on top of the LFH in the sterile non-hazardous cleanroom.

l) A damaged label on the (b) (4) laminar flow hood (LFH) in the sterile non-hazardous cleanroom, with material flaking off on the right side of the label.

m) Exposed wood on the (b) (4) connecting sterile cleanrooms to adjacent spaces.

n) A metal cart stored in the sterile hazardous cleanroom with several long scratches in its top surface.

o) Soiled lower surfaces on two carts stored along the west side of the sterile hazardous cleanroom, and on the bottom shelf of the metal storage rack used to hold the LFH and (b) (4) in the sterile non-hazardous cleanroom.

On 11/29/22, the (b) (4) hood was observed to be used in the production of 100 mL of Niacinamide 100 mg/mL injectable solution, lot 112922JF@(b) (4).

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**OBSERVATION 3**

You produced hazardous drugs without providing adequate containment to prevent cross-contamination.

Specifically,

Your records used to document the pressure differential between the ISO 7 sterile hazardous cleanroom and the adjacent ISO 7 anteroom showed that the pressure differential between these two rooms was below your established specification of (b) (4) and therefore did not pass the check during (b) (4) checks (b) (4) between 10/10/22 and 11/30/22, with the exception of 11/02/22. The ISO 7 sterile hazardous cleanroom and the adjacent ISO 7 anteroom were both regularly used in the production of sterile drugs throughout this period.

The differential pressure gradient between the anteroom and sterile hazardous cleanroom is designed to prevent the movement of air from the sterile hazardous cleanroom into the anteroom, and the recorded measurements show a pervasive differential below the lower limit of the pressure differential designed to maintain this separation. The differential pressure gradients between the rooms in your "compounding area" are set so that the air in the anteroom flows into the ISO 8 gowning room, and then into the unclassified pharmacy area where non-sterile, non-hazardous drug products are produced. Your firm's management estimated that approximately (b) (4) % of the drug products produced by your firm contain hazardous and/or highly potent materials.

**OBSERVATION 4**

Unsealed, loose ceiling tiles were observed in your cleanroom.

Specifically,

a) On 11/28/22, an unsealed ceiling tile was observed directly above the ISO 5 biosafety cabinet (BSC) in your ISO 7 sterile hazardous cleanroom.

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b) While witnessing the cleaning of your ISO 7 sterile non-hazardous cleanroom on 12/02/22, I observed that the ceiling tile in the northwestern corner of this room became pushed up out of the frame in which it was seated while being wiped with a fabric mop head. On 11/29/22, the (b) (4) (b) (4) hood installed in this room was observed to be used in the production of 100 mL of Niacinamide 100 mg/mL injectable solution, lot 112922JF@(b) (4).

## OBSERVATION 5

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,

Your firm did not perform analytical testing on drug products lots produced by your firm to ensure the identity and strength of active ingredients prior to distribution, including the following:

a) Lidocaine 5% Topical Solution, 3000 mL, produced on 09/14/22 and 10/13/22 to fill Rx (b) (6), (b) (7)(C) on 9/13/22 and 10/17/22 respectively.

b) Dyclonine 10 mg/mL oral suspension, 480 mL, produced on 09/14/22 and used to fill Rx (b) (6), (b) (7)(C) on 09/14/22.

## OBSERVATION 6

The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist.

Specifically,

a) Your firm did not perform identity or any other analytical testing on multiple raw materials used in the production of two 3000 mL lots of Lidocaine 5% Topical Solution, produced on 09/14/22 and

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10/13/22 to fill Rx (b) (6), (b) (7)(C) on 9/13/22 and 10/17/22 respectively, including the following:

- Lidocaine, NDC (b) (6) exp April 2026
- Propylene Glycol, NDC (b) (4), exp 02/23/24
- Methylparaben, NDC (b) (4), exp 07/01/23
- Propylparaben, NDC (b) (4), exp 12/13/22

b) Your firm did not perform identity or any other analytical testing on multiple raw materials used in the production of a 480 mL lot of Dyclonine 10 mg/mL oral suspension, produced on 09/14/22 and used to fill Rx (b) (6), (b) (7)(C) on 09/14/22, including the following:

- Dyclonine HCl, NDC (b) (4), exp 03/19/24
- Menthol, NDC (b) (4), exp February 2023
- Polysorbate, NDC (b) (4) exp July 2023
- Propylene Glycol, NDC (b) (4), exp 02/23/24

## OBSERVATION 7

Media fills do not adequately simulate the most challenging or stressful conditions.

Specifically, the media fill operation used to re-qualify one of your technicians for sterile operations on 08/24/22 consisted of the preparation of three 5 mL bottles of Tryptic Soy Broth 3% Solution plus a 5 mL control bottle. On 12/05/22, that same technician stated that your firm produces lots that are as large as (b) (4) 50 mL vials of sterile drug product. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

## *DATES OF INSPECTION

11/28/2022(Mon), 11/29/2022(Tue), 11/30/2022(Wed), 12/01/2022(Thu), 12/02/2022(Fri), 12/05/2022(Mon), 12/06/2022(Tue), 12/07/2022(Wed), 12/09/2022(Fri)

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X Christopher R Czajka
Investigator
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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."