DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115 Industry Information: www.fda.gov/oc/industry	3/7/2023-4/5/2023
	FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jarred D. Dudding, QA Director and Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
Apollo Care, LLC	3801 Mojave Ct Ste 101
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Columbia, MO 65202-4042	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) (WE) OBSERVED:

OBSERVATION 1

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,

A. An 8.000% leak (against a specification of (b) (4)) was found in your ISO 5 laminar airflow hood, number (b) (4) , in (b) (4) lab (b), during third party certification activities on 02/02/2023. You stated (b) (4) of the sterile drug products compounded by your firm are aseptically filled in this hood. You reviewed the certification report on 02/17/2023 and did not open a deviation or investigation to determine the potential impact on the approximately (b)(4) batches of sterile drug products filled in this hood since the last time the HEPA filter passed an integrity test on 06/20/2022. In addition, you do not have any scientific rationale for the (b)(4) HEPA filter repair on the 8% leak. Furthermore, there is no documentation to support the lack of a full recertification of the hood after the patching occurred.

Based on your beyond use dates (BUD), approximately (b)(4) batches of these sterile drug products were still within expiry as of 03/20/2023. The sterile drug products potentially impacted by this HEPA filter leak include, but are not limited to, the following:

-Fentanyl 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (0.1%) added to 250mL IV bag 0.9% Sodium Chloride Injection (For Epidural Use Only), batch number (b) (4)
-Fentanyl 50mcg/mL (2,500mcg Total Dose) 50mL Syringe (Injection for Intravenous Use Only), batch number (b) (4)
-Vancomycin 1.5g added to 500mL of 0.9% Sodium Chloride (Injection for Intravenous Use Only), batch number (b) (4)

THIS IS A REPEAT OBSERVATION FROM THE 2018 INSPECTION

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	Carl A Huffman III Conner N. Mann Wayne D. McGrath	CARL A HUFFMAN III, CSO Conner N. Mann, CSO Wayne D. McGrath, CSO	4/5/2023

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B. The following discrepancies were identified during review of your open investigation, number IR-23-002, in response to finding suspect microbial growth on approximately (b) (4) labels of Fentanyl 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (0.1%) added to 250mL IV bag 0.9% Sodium Chloride Injection (For Epidural Use Only), batch number (b) (4), on 01/24/2023:

-You did not perform identification testing on the suspect microbial growth.

-You did not perform any enhanced or expanded environmental monitoring in classified or unclassified areas as a result of the suspect microbial growth findings.

-You removed the outer (b) (4) bags from the Fentanyl 500mcg (2mcg/mL) and Ropivacaine HCl 250mg (0.1%) added to 250mL IV bag 0.9% Sodium Chloride Injection (For Epidural Use Only) without stability data or an adequate impact assessment to determine the impact on your beyond use dates for this product. Approximately (b) (4) units of this product from batch (b) (4) were observed without outer (b) (4) bags in the (b) (4) storage room on 03/07/2023.

-You assumed this was the same microbial contamination as a previous event in July 2022 with no scientific evidence.

C. The following discrepancies were identified during review of your closed investigation, number IR-22-004, in response to finding suspect microbial growth on one label on Norepinephrine 8 mg added to 250 mL IV bag of 5% Dextrose Injection, batch number (b) (4), on 07/01/2022:

-The IV bag with the suspect microbial growth was wiped down and relabeled for distribution.

-The investigation states the suspect microbial growth was identified as Trichoderma harzianum and states this organism is unlikely to cause illness or harmful health implications in humans.

-The investigation states future drug products held at room temperature would not be placed in bags but does not assess the impact on the light sensitive drug products.

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D. The following discrepancies were identified during review of your closed deviation investigation, number D-22-067, into contaminated media plates, lot number (b) (4) , received from your media plate supplier, which you initiated on 09/06/2022 and listed the duration of the event as 08/15/2022 to 09/15/2022:

-Deviation report number D-22-067 states "There has been a noticeable increase in growth on samples taken. Any alert and/or action limits exceeded will be disregarded for the stated lots." The deviation report later states "All affected lots will be released pending product testing results." The deviation report lists (b) (4) batches of drug products that were affected, including, but not limited to, batch number (b) (4) (Vancomycin 1.5 mg added to 500 mL IV bag of 0.9% Sodium Chloride for injection), batch number (b) (4) (Fentanyl 50 mcg/mL in 50 mL IV bag for injection), and batch number (b) (4) (Fentanyl 2 mcg/mL and Ropivacaine HCl 250 mg added to 250 mL IV bag of 0.9% Sodium Chloride for epidural).

-CAPA report number 22-033 states "EM to continue with suspect plates, however no interpretation of growth to be completed."

-There was no formal investigation into the contaminated plates or the potential impact on sterile drug products compounded during this time.

-The contaminated plates were still used and brought into ISO 8 and ISO 7 classified spaces.

-The batch records affected by deviation D-22-067 list "N/A" on the environmental monitoring sections with no further explanation of whether or not microbial growths were obtained.

OBSERVATION 2
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically,

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A. As of 03/20/2023, your firm has never performed a media fill using 10 mL syringes. In December 2022, your firm began commercially compounding Ketamine 50 mg per 5 mL (10 mg/mL) in 10 mL syringes and you began distributing them in January 2023. In addition, your recent media fill, conducted on 09/06/2022, was only performed using 30 mL syringes. As of 03/20/2023, you stated your firm only distributes 10 mL and 50 mL syringes and you do not commercially compound any drug products in 30 mL syringes.

B. The following discrepancies were identified during review of your visual inspection qualification program:

-Your employees have never been qualified on visually inspecting syringes. Your firm compounds multiple sterile drug products in syringes, including, but not limited to, Fentanyl 50 mcg/mL in 50 mL syringes for injection and Ketamine 50 mg per 5 mL in 10 mL syringes for injection.

-Your employees have never been qualified on visually inspecting and identifying critical defects in IV bags. Your QA Director, JDD, stated the visual inspection qualification (b) (4) do not contain critical defects in IV bags, but instead use (b) (4) with critical defects. Your firm does not compound drug products in (b) (4) In addition, your visual inspection qualification reports do not list defect categories such as minor, major, and critical.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

Specifically,
On 03/10/2023, we observed an employee move a (b) (4) beaker of non-sterile Vancomycin bulk solution from the ISO 7 (b) (4) room into the ISO 5 hood without first wiping down the bottom of the beaker with (b) (4) . Your SOP number PRC001.1, Cleanroom Activity and Aseptic Technique, requires supplies to be disinfected when placed into the direct compounding area in the ISO 5 hood.

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OBSERVATION 4

Drug products are not stored under appropriate conditions of light so that their identity, strength, quality, and purity are not affected.

Specifically,
The following drug products are not stored in a manner to protect them from light:

-Norepinephrine 4mg added to 250mL of 5% Dextrose (Injection for Intravenous Use Only) - Lot (b) (4)
-Norepinephrine 8mg added to 250mL of 5% Dextrose (Injection for Intravenous Use Only) - Lot (b) (4)
-Norepinephrine 8mg added to 250mL 0.9% Sodium Chloride (Injection for Intravenous Use Only) - Lot (b) (4)
-Fentanyl 500 mcg & Ropivacaine HCl 250 mg added to 250 mL 0.9% Sodium Chloride - lot (b) (4)

OBSERVATION 5

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

A. The established name of the drug

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

• Ketamine Injection 50 mg per 5 mL (10 mg/mL) Single-Use Syringe

B. The storage and handling instruction

Examples of drug product label where storage and handling instruction is not included:

• Norepinephrine 4 mg added to 250 mL of 5% Dextrose
• Norepinephrine 8 mg added to 250 mL of 5% Dextrose
• Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride

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OBSERVATION 6

The container of your outsourcing facility's drug products is missing the container label and does not include information required by section 503B(a)(10)(B).

Examples of drug products without containers labels:

- Fentanyl 50 mcg/mL (2,500 mcg Total) in 50 mL Syringe
- Ketamine Injection 50 mg per 5 mL (10 mg/mL), Single-Use Syringe
- Phenylephrine HCl Injection 1 mg per 10 mL (100 mcg/mL), Single-Use Syringe
- Succinylcholine Cl Injection100 mg per 5 mL (20 mg/mL), Single-Use Syringe
- Vancomycin in various strengths added to 0.9% Sodium Chloride, IV bag
- Midazolam 1mg/mL (100mg) 100mL IV Bag
- Norepinephrine 4 mg added to 250 mL of 5% Dextrose
- Norepinephrine 8 mg added to 250 mL of 5% Dextrose
- Norepinephrine 8 mg added to 250 mL 0.9% Sodium Chloride
- Fentanyl 500 mcg (2 mcg/mL) and Ropivacaine HCl 250 mg added to 250 mL 0.9% Sodium Chloride Injection IV bag

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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 judgement, 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."