DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
USFDA 8050 Marshall Dr. Suite 205 Lenexa, 66214 Email Responses To: Program Division Director ORAPHARM3_RESPONSES@fda.hhs.gov	08/16, 17, 18, 19, 20, and 09/08/2021
	FEI NUMBER 3013927023

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Jarred D. Dudding, Quality Assurance Director, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Apollo Care, LLC	3801 Mojave Court, Suite 101
CITY, STATE AND ZIP CODE Columbia, MO 65202	TYPE OF 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.
The observations noted in this Form FDA 483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM (I)(WE) OBSERVED:

Observation 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed. Specifically,

A. During finished product testing, the potency for lot (b) (4) of Vancomycin 1.5g in 500 mL 0.9% Sodium Chloride was found to be 116.1%, which was above the listed specification of (b) (4) Your investigation report, number IR-19-001, for this OOS lists the preliminary root cause as pump overfill, but then changes to laboratory error based on the (b) (4) analysis results. However, the contract laboratory performing the potency testing stated they could not invalidate the original OOS result because the original sample was not stored as directed and could have degraded, which rendered it unfit for an adequate retest. After receiving the OOS results, you submitted (b) (4) additional units for potency testing, which came back within specification at 103.0%, 100.7%, and 105.5%. You accepted the resample results and released this lot for distribution on 08/15/2019.

B. During finished product testing, the potency for lot (b) (4) of Norepinephrine 8mg/250mL D5W was found to be 115.2%, which was above the listed specification of (b) (4) Your investigation report, number IR-19-002, for this confirmed OOS lists the probable root cause as pump overfill due to the (b) (4) pump having inherent fill variance and possibly not holding its calibration. After receiving the OOS results, you submitted (b) (4) additional units for potency testing, which came back within specification at 113.9%, 114.3%, and 113.9%. You accepted the resample results and released this lot for distribution on 09/10/2019.

Observation 2

Procedures designed to prevent objectionable microorganisms in drug products purporting to be sterile are not established, written, and followed.

A. On 08/19/2021, during aseptic filling operations of Vancomycin, 1500mg in 250 mL of Sodium Chloride IV bags, lot (b) (4), I observed your employee using (b) (4) to wipe down the medication ports on the bags outside of the ISO 5 hood prior to placing them in the ISO 5 hood in (b) (4) Laboratory (b) (4) which is classified as ISO 7. A second employee then pierces the medication ports of each bag with a (b) (4) needle to add the Vancomycin to the 250 mL of Sodium Chloride without sterilizing the medication port in the ISO 5 environment.

B. Gowning to enter the ISO7 area is performed in the ISO8 Anteroom (b) (4) On (b) (4) while observing aseptic filling operations of Vancomycin, 1500 mg in 250 mL of Sodium Chloride IV bags, lot (b) (4), we observed employees moved frequently between the ISO7 ((b) (4) Lab (b) (4)) and the ISO8 hallway (Anteroom (b) (4)) to retrieve other items such as additional Sodium Chloride IV bags. We observed that this was done without changing

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of gowning or changing sterile gloves. Anteroom (b)(4) is a hallway where the handwashing sink and storage for gowning equipment is located.

Observation 3

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

A. On 8/19/21 during the (b) (4) setup for Bulk Fentanyl Citrate Solution in the (b) (4) Lab the compounding technician did not have any environmental monitoring in the LAF ((b) (4) when making the connection to the (b) (4) assembly. The firm did not take active (b)(4) samples during this critical operation. A (b) (4) plate was added only after sterile bulk receiving bag was attached to the (b) (4) side (sterile side) of the (b) (4) . In addition, the firm had no nonviable particulate monitoring in the ISO5 throughout all operations for (b) (4) of this bulk. The bulk Sterilized Drug product solution was used to make Fentanyl Citrate, 50 mcg/mL in 50 mL syringes, lot (b) (4) .

B. On (b) (4) , during the compounding of Fentanyl Citrate, 50 mcg/mL in 50 mL syringes, lot (b) (4) , I observed your employee perform the aseptic connection of the bulk bag of Fentanyl Citrate solution to the pump on the far left-side of the ISO 5 hood in (b) (4) Laboratory (b)(4) . A (b) (4) plate was present; however it was located approximately three feet away on the right-side of the ISO 5 hood during the aseptic connection. In addition, you were not performing active (b)(4) sampling when the aseptic connection was performed.

C. You had your (b) (4) Particle Counter (equipment ID number (b) (4)) calibrated on 01/04/2021. You stated this is your (b) (4) particle counter and it was sent out for multiple days due to COVID-19 delays, but you were unsure exactly how long it was absent from your facility. Your firm compounded multiple products on (b) (4) without the use of a non-viable particle counter, including, but not limited to, Vancomycin 1250 mg in 250 mL IV bag, lot (b) (4) , and Norepinephrine 8 mg in 250 mL IV bag, lot (b) (4) . Per your SOP CQI003.1, Clean Room Monitoring, effective 03/01/2021, (b)(4) (b) (4) . The SOP then states "all ISO 5 areas (b) (4) ."

Observation 4

Aseptic Processing areas are deficient in that the floors, walls, ceilings, and work surfaces are not smooth and/or hard surfaces that are easily cleanable. Specifically,

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A. On 08/17/2021, we observed:

1. The work surfaces (bench tops) of all (b) (4) ISO5 LAF workstations ((b) (4) and (b) (4)) are made up of laminated material which is seamed on the side panels. In one instance on the front left edge of (b) (4) the laminate had cracked off and been repaired. Your firm has not performed any cleaning/disinfecting studies of any kind nor do you have any data indicating that this material is appropriate for use inside the ISO5 aseptic area.

2. There were four instances within the ISO7 (b) (4) Lab (b) (4) which is the background area for the ISO5 workstation, where the ceiling tile caulk is coming apart and white string like pieces approximately 2 cm long were hanging from the ceiling.

3. There was what appeared to be adhesive residue on the entry door wall in the ISO7 area of the (b) (4) Lab that cause a rough area on the otherwise smooth, hard surface and may cause this area to be more difficult to sanitize.

4. A screw head was observed protruding from the area below the adhesive residue on the entry door wall in the ISO7 area of (b) (4) Lab.

5. Adhesive residue on the entry door wall in the ISO7 area of (b) (4) Lab (b) (4)

6. A screw head was observed protruding from the area below the adhesive residue on the entry door wall in the ISO7 area of (b) (4) Lab (b) (4)

B. On 08/19/21, we observed swinging doors leading from the ISO 8 hall (Anteroom (b) (4) to the ISO 7 rooms. The ISO 7 rooms include (b) (4) Lab (b) (4) and the (b) (4) Lab. The doors swing open into the ISO 8 hall and are equipped with brush style door sweeps at the bottom. There was apparent dirt, fibers, and other debris in the door sweep brushes and it also appeared bristles were missing from the brushes. Your firm does not have a cleaning or maintenance program for the door sweeps.

Observation 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the (b) (4) process. Specifically,

A. Your firm's current laminar airflow studies (smoke studies) of the ISO5 Horizontal Laminar Airflow Workstations were not performed under conditions showing aseptic operations that are representative of your current

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compounding practices nor did they emulate all critical unit operations and interventions used during compounding of your sterile drug products.

B. Media Fill Records for Family II (Batch (b) (4)) and Family III (Batch (b) (4)) do not accurately represent current manufacturing practices in that:

1. Your firm receives (b) (4) that are not connected to the (b) (4) bag and must be (b) (4) connected to the tubing both (b) (4) and (b) (4) of the (b) (4) . Connections of the (b) (4) to the (b) (4) bag used as the receiving vessel for the sterilized bulk product represent a possible route of microbial contamination. In addition we observed that the spike used to connect tubing on the (b) (4) of the (b) (4) may be left hanging from its tubing in the ISO 5 for minutes while a new (b) (4) bag is prepared. The firm does not simulate this operation during media fills.

2. Neither your media fill procedures nor your executed media fill records indicate you emulated active (b) (4) sampling monitoring or placing a (b) (4) plate in a specific location for viable environmental monitoring while sterilizing the prepared media.

3. Neither your media fill procedures nor your executed media fill records indicate you emulated active (b) (4) sampling monitoring or placing a (b) (4) plate in a specific location for viable environmental monitoring while connecting the prepared media in the (b) (4) bag to the transfer tube set during filling.

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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."