DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA / CDER 10903 New Hampshire Ave., Bldg 51 Rm 4225 Silver Springs, MD 20993 1 301 796 3334	5/19/2025 – 6/6/2025 FEI NUMBER 3009925820
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Artis L. Terrell Jr., President and CEO	
FIRM NAME	STREET ADDRESS
Medi-Fare Drug Pharmaceutical Compounding, LLC	300 West Pine Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Blacksburg, SC 29702	Sterile Drug Manufacturer

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: Products impacted include but are not necessarily limited to Fentanyl 10mcg/mL in 250mL bags.

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. I visually observed contaminated / stained HEPA filter affecting ISO 5 hood #(b) (4) In addition to hood #(b) (4), hood #(b) (4) and hood #(b) (4) also have apparent contamination / stains. To date, no investigation has been opened regarding this apparent contamination.

B. You lack a scientifically established qualification process regarding your media fill unit inspections. You have not demonstrated, via training and qualification, that personnel can accurately and repeatedly detect failing units.

C. You rejected lot (b) (4) of repacked Proparacaine HCl 0.5% due to (b) (4) sterile caps coming off of your(b) (4) syringes during production. You documented this via INC-24-014 which records the use of(b) (4) caps lot #(b) (4) These caps had not been scientifically evaluated prior to use to include actions including but not limited to change control, process validation and / or media fills. After this batch rejection, you documented CAPA-24-005 which includes the use of a new vendor cap. While

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CAPA-24-005 requires container closure integrity testing of approximately (b) (4) units it does not require such actions as process validation, stability testing and / or media fills.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

Specifically,

A. I observed apparent white colored residue and apparent brown or red colored stains on your (b) (4) work surfaces in your ISO 5 hood # (b) (4) The apparent white colored residue is also apparent throughout your ISO 5 environment affecting approximately all hoods # (b) (4) The design with the (b) (4) approximate (b) (4) of your (b) (4) working surfaces offers hard to clean surfaces. To date, no investigation has been opened regarding this apparent contamination.

B. You have failed to confirm and maintain the cleanliness of your ISO 5 environments.

1. You use (b) (4) to generate smoke during your (b) (4) airflow pattern evaluations. You have not performed testing to support the adequacy of your cleaning procedures for the presence or absence of (b) (4) after you have cleaned and sanitized your ISO 5 environments.

2. I observed cleaning and sanitizing activities using (b) (4) on 5/19/2025 which included ISO 5 hood (b) (4) I observed your ISO 5 surfaces began to dry no later than (b) (4) and become fully dry at approximately (b) (4) post cleaning and sanitizing activities. Your written procedures require you to maintain contact times of (b) (4) for (b) (4).

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OBSERVATION 3

The separate or defined areas and control systems necessary to prevent contamination or mix-ups are deficient.

Specifically,

A. The design of your facility allows for operations to include material flows directly between unclassified areas and your ISO 7 sterile compounding room, "Room(b) (4)". Specifically, materials flow from your non-classified "Prep Room" to your ISO 7 compounding room, "Room(b) (4)" and from "Room (b) (4)" to your non-classified room, "Quarantine Area". Non-classified areas lack continuous monitoring of differential pressures as well as non-viable particles.

B. Air pressure differential limit setpoint alarms and alarm delays are not scientifically established nor monitored regarding your ISO 7 room where you produce sterile drug product(s). You did not establish real-time setpoint limit alarms according to your written SOPs such that your SOP requires differential pressures of (b) (4) W.C. Your actual alarm limits are(b) (4) W.C. Furthermore, you established alarm delays of approximately (b) (4) per your electronic monitoring system and / or vendor as well as your Quality Director. Your written SOPs lack reference to any air differential alarm delays.

REPEAT

OBSERVATION 4

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

Specifically,

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A. Personnel and environmental monitoring during and after your aseptic connection as well as throughout aseptic production is not scientifically performed.

1. The system by which you conduct personnel monitoring is not scientifically established. I observed personnel enter your ISO 5 environment with their hands and arms. You do not currently routinely perform personnel monitoring regarding production personnel forearms.

2. I observed aseptic operators perform finger-tip personnel monitoring after performance of the aseptic connection unit step which includes bulk filling. However, multiple glove changes occurred during this process.

B. Non-Viable Particle (NVP) monitoring is conducted in the ISO 5 hoods. This NVP monitoring is not continuously performed. Furthermore, the firm produces sterile drug products in multiple ISO 5 hoods concurrently and only owns one NVP monitoring device.

OBSERVATION 5

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, you have not certified that (b) (4) water is sterile and nonpyrogenic whereby it is accompanied by a valid COA to ensure the reliability of the supplier's Certificate of Analysis. (b) (4) water is used in the production of sterile drug products to include Fentanyl(b) (4) , lot(b) (4) in(b) (4) bags.

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OBSERVATION 6

Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

A. I observed particulate matter on 5/20/2025 in approximately (b) (4) syringes which were a part of your media fill lot (b) (4). These syringes were previously inspected by your firm on 5/07/2025 and 5/15/2025 and were not identified with particulate matter.

B. You documented INC-24-024 on 11/5/2024 for surface plate (b) (4) regarding ISO 5 hood # (b) (4) was observed with "overgrowth" of Rhizopus-oryzae. Lot (b) (4) (b) (4) of Phenylephrine was rejected. Your root cause was inconclusive, and you did not document additional CAPA actions to address this failure.

OBSERVATION 7

An adequate number of batches of each drug product are not tested to determine an appropriate expiration date.

Specifically,

You discontinued your stability program in approximately 2018 per your site leadership personnel. You have continued to produce various drug products to include but not limited to Fentanyl (b) (4), lot (b) (4) in (b) (4) bags, Succinylcholine (b) (4), lot (b) (4) in (b) (4) syringes. Succinylcholine is produced in lots of (b) (4), (b) (4) syringes.

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OBSERVATION 8

Written procedures are not established, written and followed that describe the in-process controls, tests and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically,

A. You lack establishment of scientifically justifiable in-process limits regarding visual inspection. Your limit is (b) (4) %, in aggregate for your 100% inspection in addition to your post 100% inspection sample(s). You have not established limits specific to individual defect categories to include but not limited to leakers and particulate matter. You have detected units with fibers and leaking units during your 100% inspection.

B. You lack use of adequate equipment (b) (4)) regarding visual inspection. You currently utilize (b) (4) backgrounds without adequate lighting.

C. You do not comprehensively document your post 100% inspection sample to support the sample is appropriate numerically and that it represents the entire batch.

OBSERVATION 9

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

A. Your visual inspection qualification training is inadequate regarding both your initial qualification and your lack of requalification.

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1. You lack an annual requalification process.

2. Your initial qualification is not scientifically established nor standardized. Your initial visual inspection qualification is conducted via On-the-Job Training only. While you have a defect kit, it is not used to qualify your operators.

3. Your initial qualification process lacks assurance that operators are trained to observe and detect critical, major, and minor defects.

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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."