DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	2/11/2025-2/21/2025* FEI NUMBER 3003829708

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Janice L. Erickson, Owner

FIRM NAME	STREET ADDRESS
Meds For Vets	9550 S State St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sandy, UT 84070-3211	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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

1)The air pressure gauge used to perform post (b) (4) (b) (4)) of all (b) (4) have never been calibrated. The air pressure gauge is used to ensure the (b) (4) of the (b) (4) . (b) (4) for both human and animal drug products, are tested using this air pressure gauge. Since 12/16/2024, your firm has dispensed approximately (b) (4) sterile drug product units that have been aseptically (b) (4)

2)The (b) (4) , model (b) (4) used to (b) (4) sterilize compounded drug products, and components used for sterile compounded drug products has not been qualified. The effectiveness of the (b) (4) sterilization cycle has not been initially validated or verified annually. In addition, your firm does not use external probes to monitor each load cycle and biological indicators are not always used during each cycle. Since 12/16/2024, your firm has dispensed approximately (b) (4) sterile drug product units that have been exposed to (b) (4) sterilization.

3)The (b) (4) , (b) (4) series (b) (4) , Model (b) (4) used to sterilize compounded drug products via (b) (4), has not been qualified. Your firm has failed to validate the effectiveness of the (b) (4) cycle, used to render drug product sterile, initially or verify effectiveness annually. Since 12/16/2024,

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	Demario L Walls, Investigator Stephanie M Mongeluzzi, FDA Center Employee	Demario L Walls Investigator	2/21/2025

your firm has dispensed (b) (4) sterile drug products exposed to (b) (4) sterilization.

4)Visual inspection of finished sterile drug products are not performed against a (b) (4) background nor adequate light used while performing visual inspection. On 2/12/2025 and 02/13/2025, I observed your firm's pharmacist perform visual inspection of a sterile drug product in (b) (4) glass vial without using a (b) (4) background or adequate light to see through the vial. In addition, your firm lacks a written standard procedure for conducting visual inspection of sterile drug products.

5)Results of the post (b) (4) ((b) (4)) are not always included in the compounding record. For example, Atropine Sulfate 0.54mg/ml – Nst Injection, lot 1629, manufacturer date 01/27/2025, beyond use date 01/31/2025, was sterilized via (b) (4) Your firm failed to record the results obtained from post (b) (4). The result of the post (b) (4) is used to determine sterility of the drug product. 200ml of Atropine Sulfate 0.54mg/ml – Nst Injection, lot 1629 was dispensed on 01/28/2025.

OBSERVATION 2

Use of ingredients not intended for pharmaceutical use in sterile drug production.

Specifically, your firm uses (b) (4) for irrigation in the production of sterile human and animal injectable drug products. For example, according to your firm's logged formula worksheet (compounding record) for Apomorphine Hcl 6mg/ml – Nst Injection (animal drug product), lot 917, beyond use date 01/17/2025, your firm used (b) (4) for irrigation, lot (b) (4) to produce this product. (b) (4) of this sterile drug product was dispensed on 01/06/2025. According to your firm's logged formula worksheet (compounding record) for Tirzepatide/B12 (methyl) 10mg/0.5mg/ml Injection (human drug product) lot 2316, your firm used (b) (4) of (b) (4) for irrigation, lot (b) (4) to produce (b) (4) of this sterile drug product. (b) (4) of this product was dispensed on 01/30/2025. The (b) (4) for irrigation used is labeled "not for injection". Your firm lacks scientific justification why

(b) (4) for irrigation is suitable for human and animal injectable sterile drug products.

OBSERVATION 3

The final and intermediate containers/closures used for drug product intended to be sterile have not been sterilized or depyrogenated.

Specifically,
Your firm has failed to validate the cleaning, sterilization, and/or (b) (4) process for drug products and drug components used in sterile compounding operations.

For example,

1) Your firm uses an unvalidated sterilization cycle for non-sterile vials purchased. In addition, your firm does not (b) (4) these vials before use. These vials are used a final container for all sterile compounded injectable drug products. Your firm does not verify that vials and/or components used for sterile drug products are pyrogen free. On 02/13/2025, I observed sterile vials staged on a cart shelf, in the ISO7 classified room, open and exposed to the environment. Sterile vials are staged in the ISO7 classified room for immediate use.

2) Reusable glassware such as but not limited to beakers, used for weighing and mixing drug products are not sterilized or (b) (4) after cleaning. According to your sterile technician, reusable glassware is cleaned in an automatic dishwasher with dish detergent and stored unwrapped in a cabinet in the unclassified lab.

OBSERVATION 4

Equipment used in the manufacture, processing, packing or holding of drug products is not of adequate size to facilitate operations for its intended use.

Specifically, your firm uses a countertop toaster oven, designed for food, to render drug products sterile via (b) (4). The toaster oven, (b) (4) Model (b) (4) is used to expose drug products to (b) (4). Your firm failed to validate the (b) (4) cycle used by this toaster oven or qualified this equipment for its intended use. Since 12/16/2024, your firm has used this toaster oven to render (b) (4) drug products sterile without validation.

OBSERVATION 5

Biological indicators were not used to verify the adequacy of the sterilization cycle.

Specifically,

1) On 02/13/2025, I observed the compound drug product Natamycin 4% - Nst Eye Drop, Lot 2465, date manufactured (b) (4), beyond use date 03/13/2025 complete a (b) (4) sterilization cycle in the (b) (4), model (b) (4) without the use of a Biological Indicator. 75ml of Natamycin 4% - Nst Eye Drop, Lot 2465, date made 02/13/2025, beyond use date 03/13/202, was dispensed on 02/14/2025.

2) On 02/17/2025, I observed a tray of clear vials and stoppers complete a (b) (4) sterilization cycle in in the (b) (4), model (b) (4) without the use of a Biological Indicator. These components are purported to be sterile and are used as final container/closures for sterile drug products.

3) The number of biological indicators used and incubated when certain drug products or components are exposed to (b) (4) sterilization or (b) (4) sterilization is not always documented in the batch record. For example, Cyclosporine 0.2% (coconut oil) Eye Drops, lot 115 was exposed to (b) (4) sterilization, however the biological indicator was not recorded in the batch record. Atropine Sulfate 1% Eye Ointment, lot 287, was exposed to (b) (4) sterilization, however the biological indicator was not recorded in the batch record.

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OBSERVATION 6

Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically,

1) On 02/12/2025 during the production of NAD+ 200mg/ml injectable, lot 2395, I observed your firm's sterile compounding technician touching multiple surfaces such as but not limited a garbage bag, door handles and the knobs of the (b) (4) (b) (4) while wearing sterile gloves. Your sterile compounding technician returned to aseptically filling the compounded drug product without changing gloves. 10ml of this sterile human drug product was dispensed on 02/14/2025.

2) On 02/13/2025 during the production of EDTA 1% eyedrops, lot 2488, made date (b) (4) , beyond use date 03/30/2025 and on 02/17/2025 during the production of Tirzepatide/B12 25mg/.05mg/ml Inj, lot 2565, beyond use date 03/31/2025, I observed your firm's sterile compounding technician touching multiple surfaces such as but limited to a bottle of (b) (4) hanging on a trash can, door handles, and non-sterile (b) (4) Your sterile compounding technician returned to aseptically filling the compounded drug product without changing gloves. Your firm dispensed 2ml of Tirzepatide/B12 25mg/.05mg/ml Inj (sterile human drug product), lot 2565, beyond use date 03/31/2025 on 02/18/2025.

3) Your firm's compounding technician was observed using a non-sterile tool during sterile production, (b) (4) contacting the inner surface of a sterile container or closure and (b) (4) touching a sterile product contact surface. For example, on 02/13/2025 during the aseptic filling of EDTA 1% Eye Drops, lot 2488, date made 02/13/2025, beyond use date 03/30/2025, I observed your sterile compounding technician use non-sterile (b) (4) that were hanging in the inside of the ISO5 Laminar Flow Hood, to apply the stopper to filled sterile vials. The

(b) (4) were used to pick up sterile stoppers and push the stoppers completely down on the filled sterile vials.

OBSERVATION 7

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

Specifically, your firm uses non-sterile cleaning wipes to clean the surfaces your of ISO5 classified Laminar Flow Hoods where sterile injectable drug products are filled. In addition, the non-sterile cleaning wipes are stored open in your ISO7 classified buffer room and your ISO8 classified ante-room.

OBSERVATION 8

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

Specifically, Media fills performed by your firm with each of the technicians/pharmacists that works in the ISO5 classified area do not closely simulate actual production conditions or cover worst-case or most challenging conditions. The media fills your firm performs has the technician/pharmacist filling media into (b) (4) vials and media into (b) (4) control vials. In routine production, your firm fills various size vials (b) (4)). Batch sizes are typically in excess of (b) (4) and can be as many as (b) (4) units.

OBSERVATION 9

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, according to your firm's most recent room/hood certification, dated 08/22/2024, conducted by (b) (4) , your firm's ISO7 classified room, used for sterile compounding of hazardous drugs, failed pressure differential testing; your firm's ISO5 classified laminar flow hood (Equipment

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ID#(b) (4) used for sterile compounding of hazardous drugs, failed site installation assessment; your firm's laminar flow hood (Equipment ID #10), used for sterile compounding, failed site installation assessment; and your firm's biological safety cabinets (Equipment ID #(b) (4) used for non-sterile compounding, failed site installation assessment.
Your firm failed to investigate product impact and corrective actions due to room and hood certification failures. Additionally, your firm failed to perform recertification of the failed Laminar Flow Hoods to ensure an ISO5 classified environment is maintained. Since the previous certification dated 08/22/2024, your firm has dispensed over (b) (4) drug products.

OBSERVATION 10
Smoke studies were inadequately performed under dynamic conditions.

Specifically, a review of your firm's smoke studies dated 02/24/2024 showed insufficient smoke being used to determine unidirectional airflow within your ISO5 classified Laminar Flow Hoods. Your firm's ISO5 classified Laminar Flow Hoods are used to aseptically fill both hazardous and non-hazardous drug products.

OBSERVATION 11
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 does not conduct routine testing for potency (assay) for all drug products produced by your firm including both sterile and non-sterile.

OBSERVATION 12
There is no written testing program designed to assess the stability characteristics of drug products.

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Specifically, your firm does not have a written stability testing program to determine Beyond Use Dates (BUD) placed on all your drug product. For example, Methimazole (anhydrous) 5mg/0.1ml Transdermal an assigned BUD of 180 days. Your firm lacks a written and approved protocol or a scientific rationale to support the assigned BUD.

***DATES OF INSPECTION**
2/11/2025(Tue), 2/12/2025(Wed), 2/13/2025(Thu), 2/17/2025(Mon), 2/18/2025(Tue), 2/19/2025(Wed), 2/20/2025(Thu), 2/21/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Demario L Walls, Investigator Stephanie M Mongeluzzi, FDA Center Employee	X Demario L Walls Investigator Signed By: Demario L. Walls -S Date Signed: 02-21-2025 19:06:23	2/21/2025

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."