DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	4/22/2024-5/10/2024* FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Melissa A. McFarland, Quality Manager

FIRM NAME	STREET ADDRESS
Brookfield Medical/Surgical Supplies, Inc.	60 Old New Milford Rd Ste 1B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brookfield, CT 06804-2429	503B 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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

A. On 04/24/2024, we observed the pre-manufacturing cleaning operations in the ISO 5 (b)(4) LFH and ISO 7 Buffer Room performed prior to manufacturing Triamcinolone Acetonide (Lot # (b) (4)). During cleaning of the ISO 5 (b)(4) LFH, operator (b)(6), (b)(7)(C) was observed leaning inside the ISO 5 (b)(4) LFH to clean the back surface of the ISO 5 (b)(4) LFH with sterile, (b) (4) .

B. The firm's smoke studies conducted in 2022 by (b) (4) were inadequate. The dynamic air flow studies were conducted using an inadequate quantity of generated smoke, which does not allow for an adequate determination that the manipulations performed by the operator do not interfere with the unidirectional airflow over and away from the product during manufacturing operations.

This is a repeat Observation from the 2022 inspection.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonathan G Matrisciano, Investigator Ogechi C Nna, Investigator Armen H Youssoufian, Investigator	X Ogechi C Nna Investigator Signed By: 2004008930 Date Signed: 05-10-2024 09:38:35	5/10/2024

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Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A. On 04/25/2024, we observed the end of the day cleaning operations performed by operator (b)(6), (b)(7)(C) in the ISO 5 (b)(4) LFH and the ISO 7 Buffer Room. During the cleaning operations the following deficiencies were observed.
   1. Operator (b)(6), (b)(7)(C) failed to clean the coved flooring "baseboard" sections of the four walls inside the ISO 7 Buffer Room.
   2. Operator (b)(6), (b)(7)(C) failed to clean a junction box and power cord located inside the ISO 7 Buffer Room.
   3. Operator (b)(6), (b)(7)(C) placed a non-sterile garbage bag inside the garbage pail located inside the ISO 7 Buffer Room.

B. On 04/25/2024, we observed the end of the day cleaning operations performed by operator (b)(6), (b)(7)(C) in the ISO 8 Ante Room. During the cleaning operations the following deficiencies were observed.
   1. Operator (b)(6), (b)(7)(C) failed to clean the bottom of the base of the (b) (4) unit prior to placing it on the cleaned tabletop located inside the ISO 8 Ante Room.
   2. Operator (b)(6), (b)(7)(C) failed to clean the scale printer located inside the ISO 8 Buffer Room.
   3. Operator (b)(6), (b)(7)(C) failed to clean the wall behind the (b) (4) Hood located inside the ISO 8 Ante Room.

C. Cleaning procedures were not followed according to your SOP 4.01 when 1 CFU was identified in an ISO 5 area during manufacturing of Triamcinolone Acetonide Lot # (b) (4) from a settle air plate. Your firm's procedure requires a (b) (4) cleaning involving objectionable organisms being recovered in the ISO 5, ISO 7, or ISO 8 area, however per the cleaning logs from 10/25-11/02/2023, only a standard cleaning was performed.

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OBSERVATION 3

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

There is no written procedure for conducting environmental and personnel monitoring (EM & PM) out of specifications (OOS) investigations. For example, an ISO 5 area EM Action Level CFU hit was documented in the batch record for Lot # (b) (4) , and there was no written procedure on investigating the EM OOS for potential product quality impact and assessing corrective action(s) per SOP 3.12 'Environmental Monitoring Program'.

OBSERVATION 4

The container of your outsourcing facility's drug products does not include information required by section 503B(a)(10)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, your containers do not include the following information:

A. Information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088; Examples of your container labels that do not contain this information:

- Betamethasone Sodium Phosphate Solution 6mg/mL 3mL
- Methylprednisolone Acetate Suspension 40mg/mL 5mL
- Methylprednisolone Acetate Suspension 40mg/mL 3mL
- Morphine Sulfate Solution 25mg/mL 10mL

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- Triamcinolone Acetonide Suspension 40mg/mL 3mL
- Triamcinolone Acetonide Suspension 40mg/mL 5mL
- Triamcinolone Acetonide Suspension 40mg/mL 1mL

B. Directions for use, including, as appropriate, dosage and administration.

Examples of your container labels that do not contain this information:

- Betamethasone Sodium Phosphate Solution 6mg/mL 3mL
- Methylprednisolone Acetate Suspension 40mg/mL 5mL
- Methylprednisolone Acetate Suspension 40mg/mL 3mL
- Morphine Sulfate Solution 25mg/mL 10mL
- Triamcinolone Acetonide Suspension 40mg/mL 3mL
- Triamcinolone Acetonide Suspension 40mg/mL 5mL
- Triamcinolone Acetonide Suspension 40mg/mL 1mL

***DATES OF INSPECTION**

4/22/2024(Mon), 4/23/2024(Tue), 4/24/2024(Wed), 4/25/2024(Thu), 4/26/2024(Fri), 4/29/2024(Mon), 4/30/2024(Tue), 5/01/2024(Wed), 5/10/2024(Fri)

X Armen H Youssoufian
Investigator
Signed By: Armen H. Youssoufian -S
Date Signed: 05-10-2024 09:39:03

X Jonathan G Matrisciano
Investigator
Signed By: Jonathan G. Matrisciano -S
Date Signed: 05-10-2024 09:39:29

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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."