DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 4/22/2024-5/10/2024* 109 Holton Street Winchester, MA 01890 3011430551 (781)587-7500 Fax: (781)587-7556 ORAPHARM1 RESPONSES@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Melissa A. McFarland, Quality Manager Brookfield Medical/Surgical Supplies, 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 LFH and ISO 7 Buffer Room performed prior to manufacturing Triamcinolone Acetonide (Lot # (b) (4)). During cleaning of the ISO 5 LFH, operator was observed leaning inside the ISO 5 LFH to clean the back surface of the ISO 5 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

Jonathan G Matrisciano, Investigator Ogechi C Nna, Investigator Armen H Youssoufian, Investigator



DATE ISSUED 5/10/2024

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

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 in the ISO 5 LFH and the ISO 7 Buffer Room. During the cleaning operations the following deficiencies were observed.
 - 1. Operator failed to clean the coved flooring "baseboard" sections of the four walls inside the ISO 7 Buffer Room.
 - 2. Operator failed to clean a junction box and power cord located inside the ISO 7 Buffer Room.
 - 3. Operator 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 in the ISO 8 Ante Room. During the cleaning operations the following deficiencies were observed.
 - 1. Operator 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 failed to clean the scale printer located inside the ISO 8 Buffer Room.
 - 3. Operator 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.

	EMPLOYEE(S)SIGNATURE Jonathan G Matrisciano, Investigator Ogechi C Nna, Investigator Armen H Youssoufian, Investigator	Ogechi C Nna Investigator Signed By 2004006930 Dalle Signed: 05-10-2024	DATE ISSUED 5/10/2024
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FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 2 of 4 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
109 Holton Street	4/22/2024-5/10/2024*			
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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			

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

FORM FDA 483 (09/08)

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

PREVIOUS EDITION OBSOLETE

SEE REVERSE OF THIS PAGE	Jonathan G Matrisciano, Invest. Ogechi C Nna, Investigator Armen H Youssoufian, Investiga:	Ogechi C Nna Investigator	5/10/2024
CODM ED A 493 (00/09)		TIONAL OBSERVATIONS	PAGE 3 of 4 PAGES

INSPECTIONAL OBSERVATIONS

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER 109 Holton Street 4/22/2024-5/10/2024* Winchester, MA 01890 3011430551 (781)587-7500 Fax: (781)587-7556 ORAPHARM1 RESPONSES@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Melissa A. McFarland, Quality Manager STREET ADDRESS Brookfield Medical/Surgical Supplies, 60 Old New Milford Rd Ste 1B CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Brookfield, CT 06804-2429 503B Outsourcing Facility

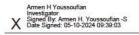
- Triamcinolone Acetonide Suspension 40mg/mL 3mL
- Triamcinolone Acetonide Suspension 40mg/mL 5mL
- Triamcinolone Acetonide Suspension 40mg/mL 1mL
- B. Directions for use, including, as appropriate, dosage and administration.

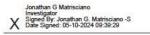
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- Triamcinolone Acetonide Suspension 40mg/mL 3mL
- Triamcinolone Acetonide Suspension 40mg/mL 5mL
- Triamcinolone Acetonide Suspension 40mg/mL 1mL

*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)





SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Jonathan G Matrisciano, Investigator Ogechi C Nna, Investigator Armen H Youssoufian, Investigator



DATE ISSUED 5/10/2024

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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."