DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	3/21/2022-4/4/2022* FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Cangelosi, President & CEO

FIRM NAME	STREET ADDRESS
Brookfield Medical/Surgical Supply, 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
Buildings used in the manufacturing, processing and holding of a drug product are not maintained in a good state of repair.

Specifically,

- Brownish rust-like material was observed on the (b) (4) bracket for the hanging bar within the interior of the firm's ISO-5 laminar flow hood. The hood is utilized for the aseptic production of the firm's solutions: Betamethasone Sodium Phosphate and (b) (4). In addition, the hood is utilized in the production of the following terminally sterilized suspensions: Methylprednisolone Acetate and Triamcinolone.

- Chipped paint was observed on the door damper on the interior side of the ISO-8 Ante Room door. The Ante Room is utilized for the following activities: sterile gowning, weighing operations and formulation activities.

- Brownish stains were observed on the bottom and sides within the Prep Room sink. The sink is located in the unclassified Prep Room and is utilized in the (b) (4) washing of the (b) (4) used for the firm's production activities.

OBSERVATION 2
Equipment and utensils are not cleaned at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Erik W Koester, Investigator Jonah S Ufferfilge, Investigator	X Erik W Koester Investigator Signed By: Erik W. Koester -S Date Signed: 04-04-2022 10:12:31	4/4/2022

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Specifically,

The firm routinely uses a household cleaner ((b) (4)) for the washing of all glassware and equipment utilized in the production of the firm's finished drug products. The firm has no evidence that the household cleaner used is capable of removing pharmaceutical residues or if there are any residues left behind on the glassware by the household cleaner.

OBSERVATION 3

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

Specifically,

The firm's smoke studies that were conducted by (b) (4) in 2021 were inadequate. The dynamic studies that were conducted for the non-terminally sterilized products (solutions) fail to include a full assessment of all ISO-7 and ISO-5 air interactions to demonstrate (b) (4) airflow and sweeping action over and away from sterile product under dynamic conditions.

OBSERVATION 4

The calibration of instruments is not done at suitable intervals in accordance with an established written program.

Specifically,

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The firm has failed to conduct a qualification (mapping) of the (b) (4) refrigerator/freezer ((b) (4)) to evaluate temperature distribution and/or uniformity. The refrigerator is utilized for the storage of Betamethasone Sodium Phosphate, USP and all environmental monitoring media (SDA & TSA).

OBSERVATION 5

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

The firm failed to define release criteria in their SOP "Visual Inspection of Sterile Drug Products", or batch records by failing to define what constitutes as a minor, major, or critical defect. Which doesn't ensure consistency of defects noted between the different qualified visual inspectors.

For example,

The firm's visual inspection is documented in the batch record which includes the following objectionable defects: Defect, Large Particle Sizes, Suspension Stuck to Vial, Volume, Suspension Height, Inert Ingredients, Color, and Growth for Suspension products and Defect, Volume, Color, Particulate, Not in Solution, Coring, Inconclusive, and Growth for Solution products. There is no definition in the batch record or SOP which establishes what constitutes as a minor, major, or critical defect. In addition, the firm's Visual Inspection test kits do not include all of the known defects such as Growth.

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***DATES OF INSPECTION**
3/21/2022(Mon), 3/22/2022(Tue), 3/23/2022(Wed), 3/24/2022(Thu), 3/25/2022(Fri), 4/04/2022(Mon)

X Jonah S Ufferfilge
Investigator
Signed By: Jonah Ufferfilge -S
Date Signed: 04-04-2022 10:13:05

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Erik W Koester, Investigator
Jonah S Ufferfilge, Investigator

X Erik W Koester
Investigator
Signed By: Erik W. Koester -S
Date Signed: 04-04-2022
10:12:31

DATE ISSUED
4/4/2022

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."