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	4/6/2017-4/18/2017*
	FEI NUMBER 3011430551

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James P. Cangelosi , Owner

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

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

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. Your firm rejected two lots of Betamethasone Sodium Phosphate PF 6mg/mL following low potency assay (Lot 120314MB (5mL) at 89.7%, Lot 110314MA (3mL) at 89.01%, specification (b) (4)). Your corrective action was to (b) (4) from (b) (4) and to (b) (4) However, your firm has still not evaluated the effect this change has on potency loss and degradation on product quality, including an evaluation of impurities and the establishment of scientifically justified impurity limits.

These inadequacies have not fully been addressed since the last inspection and your firm continues to manufacture, (b) (4) and release this product. This is a repeat observation from the **2015 FDA-483**.

B. Additionally, your firm has not evaluated the impact of (b) (4) on Methylprednisolone Acetate and Triamcinolone Acetonide Suspension for Injection.

1. Since the last inspection your firm has also had two lots of Triamcinalone Acetonide 40mg/mL Suspension for Injection fail potency testing: Lot 012116MB at 119.7%/115.4%, specification (b) (4) and Lot 072616EB at 121.3%. This product is manufactured with a (b) (4) to (b) (4) (b) (4) . The investigation again failed to evaluate the impact of (b) (4) .

AMENDMENT 1

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	Nealie C Newberger, Lead Investigator Christopher Janik, Investigator 4/18/2017 X Nealie C Newberger Nealie C Newberger Lead Investigator Signed by: Nealie C. Newberger -S	4/18/2017

2. Since the last inspection Lot 070815EA Methylprednisolone Acetate 40mg/mL suspension for Injection also failed potency specifications at 110.49%, specification (b) (4) . The cause was associated with an (b) (4) to (b) (4) . (b) (4) has currently been (b) (4) the impact of which has not been further assessed.

C. Your firm lacks rationale for not investigating lots manufactured before and after lots your firm rejected. For example, between July and October 2016, your firm rejected five lots due to presence of low CFU of objectionable microorganisms in (b) (4) air samples and the investigations lack rationale for not further evaluating lots manufactured prior and after the microbial detections.

This is a repeat citation from the **2015 FDA-483**.

OBSERVATION 2

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

Specifically, your firm references cleaning agents ((b) (4)) used to maintain a state of microbial control in your classified areas, where you manufacture Betamethasone Sodium Phosphate, Methylprednisolone Acetate and Triamcinolone Acetonide for Injection. These cleaning agents are not used in the manner intended by the manufacturer. A review of the Firm's cleaning procedures: SOP #4.01, Cleaning of the Clean Room and Ante Room, effective 2/28/2017, SOP #4.02, (b) (4) Cleaning of the Clean Room With Sporicidal Agent, effective date 8/13/2015, SOP #4.03, Cleaning of (b) (4) in Clean Room, effective date 4/12/16, and SOP #4.04 (b) (4) Cleaning Tasks, effective date 1/17/17,

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revealed that your firm has no stipulation of established contact times for cleaning with a Sporicidal agent. The firm uses (b) (4) as sporicidal agents. The manufacturer's instructions for (b) (4)

There are also no contact times listed in the SOPs for the use of (b) (4) cleaning agents or sterile (b) (4)

OBSERVATION 3

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

Specifically,

A. Your firm added a (b) (4) to the ISO5 LFH in an effort to provide a cleanable barrier over the previously exposed light bulbs; however you failed to execute a subsequent dynamic smoke study to demonstrate the (b) (4) addition does not interrupt the laminar flow of clean, first pass air.

B. On 07APR2017, your technicians were noted to carry an open (b) (4) of Betamethasone Sodium Phosphate for Injection through the ISO-8 anteroom to the ISO-7 cleanroom, without (b) (4) with sterile (b) (4) for further processing. This same practice was noted on 12APR2017 during the manufacture of Triamcinolone Acetonide Suspension for Injection. This routine practice is inadequate to prevent microbial contamination.

OBSERVATION 4

Written production and process control procedures are not followed in the execution of production and process control functions.

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Specifically, your firm has failed to demonstrate a state of control in the manufacture of Betamethasone Sodium Phosphate, Methylprednisolone Acetate, and Triamcinolone Acetonide, and continues to release lots without adequate rational when investigations referenced in Observation 1 related to super- and sub-potent product are incomplete.

***DATES OF INSPECTION**

4/06/2017(Thu),4/07/2017(Fri),4/10/2017(Mon),4/11/2017(Tue),4/12/2017(Wed),4/18/2017(Tue)

4/18/2017

X Christopher Janik

Christopher Janik
Investigator
Signed by: Christopher Janik -S

AMENDMENT 1

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