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	12/10/2018-12/21/2018* FEI NUMBER 3011430551

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

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 validate the manufacturing processes for sterile drug products. For example:

- At the time of the inspection (12/10/2018), the firm had not completed the Process Validation for the 3mL and 5mL Triamcinolone Acetonide Suspension 40mg/mL for Injection drug products.
- At the time of the inspection (12/10/2018), the firm had not started the Process Validation for the 5mL Methylprednisolone Acetate Suspension 40mg/mL for injection.

Furthermore, the firm has manufactured (b) (4) lots of Methylprednisolone Acetate Suspension 40mg/mL for injection, (b) (4) lots of Triamcinolone Acetonide Suspension 40mg/mL (3mL), and (b) (4) lots of Triamcinolone Acetonide Suspension 40mg/mL (5mL) without validating the manufacturing processes since their Regulatory Meeting with the FDA on January 8, 2018.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

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Specifically,

a. The firm does not have scientific justification for not monitoring environmental conditions throughout manufacturing operations within the ISO 5 Laminar Flow Hood (LFH). The pharmacy technicians will remove the non-viable particulate monitor from the ISO 5 LFH after (b) (4) of run time. The pharmacy technicians will remove the viable air sampler after measuring with (b) (4) each. The remaining manufacturing operations which can be (b) (4) depending on the fill size are conducted without monitoring the environmental conditions. The manufacturing activities within this hood include (b) (4) sterilized products, Methylprednisolone Acetate (40mg/mL), Triamcinolone Acetonide (40mg/mL) and one aseptically filled product, Betamethasone Sodium (6mg/mL).

b. The firm does not monitor the differential pressure of the ISO 5 Laminar Flow Hood during manufacturing operations. The firm uses this ISO 5 LFH to manufacture (b) (4) sterilized products and (b) (4) filled product on a routine basis.

The firm has manufactured and released approximately (b) (4) batches of Betamethasone Sodium (6mg/mL), 3mL; (b) (4) batches of Methylprednisolone Acetate (40mg/mL), 5mL; (b) (4) batches of Triamcinolone Acetonide (40mg/mL), 3mL; and (b) (4) batches of Triamcinolone Acetonide (40mg/mL), 5mL since April 2017.

OBSERVATION 3

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

Specifically,

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The firm failed to conduct a disinfectant efficacy study to determine the effectiveness of the cleaning agents utilized by the firm on the surfaces of the facility and equipment used in the manufacturing process of the firm's sterile drug products.

OBSERVATION 4

Each lot of a component that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

Specifically,

The firm's process for evaluating incoming Active Pharmaceutical Ingredients (Bulk Drug Substances) used to manufacture sterile drug products Methylprednisolone Acetate (40mg/mL), Triamcinolone Acetonide (40mg/mL) and Betamethasone Sodium (6mg/mL) is inadequate in that the firm has not established specifications for or routinely test for bioburden and endotoxins as part of their release specification. For example, the following was noted:

- On 08/22/2018, Betamethasone Sodium Phosphate lot number (b) (4) was used to manufacture (b) (4) vial of Betamethasone Sodium (6mg/mL) batch number 082318-1 which were released by Quality on 09/24/2018 without having endotoxin testing completed prior to use in production.
- On 10/08/2018, Methylprednisolone Acetate lot number (b) (4) as used to manufacture (b) (4) vials of Methylprednisolone Acetate (40mg/mL) batch number 100818-1 which were released by Quality on 11/02/2018 without having bioburden or endotoxin testing completed prior to use in production.
- On 10/01/2018, this lot of Triamcinolone Acetonide lot number (b) (4) was used to manufacture (b) (4) vials of Triamcinolone Acetonide (40mg/mL), 5mL lot number 100118-1 which was released by Quality on 11/19/2018 without having bioburden or endotoxin testing completed prior to use in production.

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OBSERVATION 5

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

Specifically,

On December 13, 2018, we observed the following:

- Operators (b) (6) and (b) (6) were observed moving sterile vials and equipment within the ISO-5 hood during the manufacturing of Triamcinolone Acetonide lot# 121318-1 and several instances were noted in which the top of the head and parts of the shoulders of these operators entered the hood.

- Operator (b) (6) was observed conducting end of day cleaning operations within the firm's classified areas (ISO-8, ISO-7, and ISO-5). The operator was noted to be wearing sterile gloves, a sterile hood, sterile goggles and a sterile smock. The operator's lower legs were exposed with non-sterile scrubs, socks and footwear during the cleaning operations.

OBSERVATION 6

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

Specifically,

- The firm utilizes balance (b) (4) in the weighing of all (b) (4) raw materials used to manufacture the firm's finished drug products. The firm conducts calibration of the balance prior to use with the following certified weights: (b) (4) Review of the firm's batch records for Methylprednisolone Acetate revealed that the firm routinely weighs the Methylprednisolone Acetate active ingredient in increments of (b) (4) and the (b) (4) raw material in increments of (b) (4).

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- The firm utilizes pH meters to check the pH of the formulation prior to filling of the firm's finished drug products. The firm conducts calibration of the pH meter with the following pH buffer solutions: (b) (4) (b) (4) Review of the firm's batch records for Betamethasone Sodium Phosphate revealed that the pH specifications for the Betamethasone drug product are between (b) (4) – (b) (4)

OBSERVATION 7

The firm has failed to collect retain samples for any of the finished drug products (Triamcinolone Acetonide, Methylprednisolone Acetate and Betamethasone Sodium Phosphate) that have been manufactured since the firm began operations in 2015.

OBSERVATION 8

You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2).

Specifically,

You compound drug products that: a) are identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

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Examples of compounded drug products that are essentially a copy of one or more approved drugs include: Methylprednisolone Acetate Suspension 40mg/mL and Triamcinolone Acetonide Suspension 40mg/mL.

***DATES OF INSPECTION**

12/10/2018(Mon), 12/11/2018(Tue), 12/12/2018(Wed), 12/13/2018(Thu), 12/14/2018(Fri), 12/21/2018(Fri)

X Erik W Koester
Investigator
Signed By: Erik W. Koester -S
Date Signed: 12-21-2018 11:12:45

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