

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER US Customhouse Rm900 2nd & Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	DATE(S) OF INSPECTION 6/28/2017-7/6/2017* PET NUMBER 3013456913
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Christine M. Miller , Pharmacist in Charge

FIRM NAME Biomed PA Inc. dba Soleo Health	STREET ADDRESS 950 Calcon Hook Rd Ste 15
CITY, STATE, ZIP CODE, COUNTRY Sharon Hill, PA 19079-1822	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Products

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 I OBSERVED:
OBSERVATION 1**

Specifically, on 6/28/17, during the production of Ceftriaxone Sodium 2mg

- a. The technician was observed vigorously shaking product inside of the ISO 5 area after addition of a diluent to aid in dissolution of lyophilized powder.
- b. The technician was observed vigorously waving hands inside the ISO 5 area in an effort to aide in drying after application of sterile (b) (4)

OBSERVATION 2

Specifically,

- 1. A spray bottle was observed in the ISO 7 Buffer Room. The firm reported that the spray bottle contains (b) (4) used to clean up residue resulting from spills in the ISO 5 area. The spray bottle is non-sterile but sanitized using sterile (b) (4) .
- 2. Disinfecting agents and cleaning wipes used in the ISO 5 area are not sterile.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Thomas E Friel, Investigator	DATE ISSUED 7/6/2017
		<input checked="" type="checkbox"/> Thomas E Friel Investigator Signed by: Thomas E. Friel-S

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3. The contact time for (b) (4) is insufficient to achieve sporicidal effect.

***DATES OF INSPECTION**

6/28/2017(Wed),7/06/2017(Thu)

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Thomas E Friel, Investigator

7/6/2017

DATE ISSUED

7/6/2017

X Thomas E Friel
Thomas E Friel
Investigator
Signed by: Thomas E. Friel-S