U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 14, 2018

Melanie Zimmerman, Executive Secretary
Pennsylvania State Board of Pharmacy
PO Box 2649
Harrisburg, PA 17105-2649

Dear Ms. Zimmerman:

The purpose of this letter is to refer to the Pennsylvania State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by the Pennsylvania BOP, Biomed PA, Inc., dba Soleo Health (Biomed), located at 950 Calcon Hook Road, Suite 15, Sharon Hill, PA 19079-1822 (Pharmacy License #PP481437).

FDA inspected the firm from June 28, 2017, to July 6, 2017. The Pennsylvania BOP was informed of the inspection but did not accompany the FDA investigator during the inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM572866.pdf, with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for products compounded by Biomed and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes. In the response to the Form FDA 483, received on July 21, 2017, the firm states that it "only fills prescriptions for individual patients pursuant to a valid prescription from a prescriber as required by Section 503A of the Drug Quality and Security Act."

During the inspection, the FDA investigator observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. Personnel were observed moving rapidly in the ISO 5 area, which could disrupt the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.

2. Non-sterile disinfecting agents and non-sterile wipes were used in the ISO 5 area.

3. The contact time for the sporicidal used in the ISO 5 area was inadequate to achieve sporicidal effect.

4. A non-sterile spray bottle containing a solvent was used to clean spills in the ISO 5 area.

Biomed committed to FDA in its response to the Form FDA 483, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Pennsylvania BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies.

If you have additional questions, please contact Yvette Johnson, Compliance Officer by phone at (215) 717-3077, or by email at yvette.johnson@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300011579, cn=Diana Amador-toro -S
Date: 2018.05.14 15:10:45 -04'00'

Diana Amador-Toro
Division Director/OPQO Division 1
New Jersey District Office

Cc: Biomed Pharmaceuticals