U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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July 29, 2019

Anthony Rubinaccio
Executive Director
New Jersey State Board of Pharmacy
PO Box 45013
Newark, NJ 07101

Dear Mr. Rubinaccio:

The purpose of this letter is to refer to the New Jersey 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 New Jersey State BOP, PharmScript, LLC, located at 150 Pierce Street, Somerset, NJ 08873-4185 (Pharmacy License #28RS00667000).

FDA inspected the firm from July 30, 2018, to August 7, 2018. The New Jersey State BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/media/120772/download. , 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 investigators reviewed a small sample of records for products compounded by PharmScript, LLC 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.

During the inspection, the FDA investigators 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. The firm handled beta-lactam drug products without providing adequate containment, segregation, or cleaning of work surfaces to prevent contamination.

2. The firm did not use a sporicidal agent to disinfect the ISO 5 aseptic processing area.

3. Cleanroom operators exposed skin and hair within the ISO 5 aseptic processing area.

4. Cleanroom operators touched equipment located outside of the ISO 5 aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

PharmScript, LLC, committed to FDA in its responses to the Form FDA 483, dated August 28, 2018, and September 6, 2018, 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 New Jersey State 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 James Mason, Compliance Officer, at 570 262-0519, or by email at James.Mason@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: 2019.07.29 15:32:50 -04'00'

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

Cc: PharmScript, LLC
150 Pierce Street
Somerset, NJ 08873-4185