U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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February 26, 2019

VIA UPS OVERNIGHT
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 BOP, Millers of Wyckoff, Inc., located at 678 Wyckoff Avenue, Wyckoff, NJ 07481-1430 (license # 28RS00529600).

FDA inspected the firm from April 4, 2017, to May 18, 2017. The New Jersey 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/UCM567781.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 Millers of Wyckoff, Inc., 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 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. The firm did not have sufficient disinfectant contact times to ensure adequate cleaning and disinfection of work surfaces, supplies, and equipment within the aseptic processing areas.

2. The firm's ISO 7 classified area had wooden shelves and a wooden countertop, that are difficult to clean (e.g., porous) surfaces.

3. The firm failed to adequately conduct post-use (b) (4) testing on (b) (4) used to sterilize drug products.

Millers of Wyckoff, Inc., committed to FDA in its written responses dated June 1, 2017, January 30, 2018, and March 1, 2018, to correct the deviations 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 any human or animal 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 Barbara Wilimczyk-Macri, Compliance Officer, at 973-331-4951 or by email at barbara.wilimczyk@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
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Date: 2019.02.26 12:04:58 -05'00'

Diana Amador-Toro
Program Division Director
Office of Pharmaceutical Quality Operations
Division I

Cc: Millers of Wyckoff, Inc.
678 Wyckoff Avenue
Wyckoff, NJ 07481