U.S. FOOD & DRUG ADMINISTRATION

July 13, 2023

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

Ref: FEI 3012223534

State Action Letter

Dear Mr. Rubinaccio,

The purpose of this letter is to refer to you, the New Jersey Board of Pharmacy (NJ BOP), for further action the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy that you license, Colonia Care Pharmacy, located at 515 Inman Avenue, Suite A, Colonia, New Jersey, 07067.

FDA's most recent inspection of this state-licensed pharmacy was on June 9, 2021 to July 26, 2021. You were informed of the inspection but did not accompany FDA investigators. Attached are copies of Form FDA 483s that document our investigators' observations from this inspection, as well as Form FDA 483s from two prior inspections of this state-licensed pharmacy conducted in 2016 and 2019.

During the most recent inspection, in 2021, FDA investigators observed deviations from appropriate compounding practice that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Our review of the evidence obtained by FDA investigators during the inspection indicates that the firm produces drug products intended to be sterile in an ISO 5-classified laminar flow glovebox (LFGI) that is in a non-classified area, without limiting beyond-use-dates (BUD) of drug products accordingly. This is a repeat observation for Colonia, noted during FDA's 2016 and 2019 inspections. In July 2019 the firm committed to a corrective action (assigning BUDs that do not exceed (b)(4) hours when stored at room temperature and (b)(4) hours when refrigerated or frozen for drug products intended to be sterile produced in the LFGI). During the 2021 inspection FDA investigators observed that these corrections had not been fully implemented.

The Form FDA-483 for FDA's 2021 inspection identifies additional deviations from appropriate compounding practice, including:

1. Production areas which contain difficult to clean, porous, particle-generating, and visibly dirty equipment and surfaces.
2. Inadequate cleaning of the ISO 5-classified area.
3. Handling hazardous and highly potent drugs without adequate controls to prevent cross-contamination.

FDA held a regulatory meeting with the firm on November 22, 2022, to discuss the contamination risk associated with their sterile drug production processes and to obtain clarification regarding the firm's commitment to appropriate corrective action. However, as of the time of this letter, the firm has not committed to appropriate corrective actions, and FDA is concerned that the contamination risk associated with the firm's practices represents a potential risk to public health.

FDA is referring this matter to you for further action to ensure that appropriate corrective action is implemented by Colonia Care Pharmacy. This state-licensed pharmacy collects patient-specific prescriptions, consistent with traditional compounding, and after considering the scope and nature of the observations we believe that you, the State regulatory authority, are in the better position to conduct follow-up and ongoing regulatory activities to ensure the quality of drug products produced by this firm. We note that on November 1, 2022, the USP published a Revised General Chapter <797> which includes standards addressing some of the compounding practices FDA has noted at this firm. Revised General Chapter <797> will go into effect November 1, 2023, but USP has encouraged early compliance. Should you want to consult us on any technical matters, please contact Compounding@fda.hhs.gov and refer to this State Action Letter.

In addition, please notify us if you become aware of any serious adverse events or product quality concerns associated with drug products made at this state-licensed pharmacy, or if you observe any practices at this state-licensed pharmacy that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of human drug compounding. When you follow up on this matter with the state-licensed pharmacy, please notify us with your findings. If you have additional questions or have information regarding your follow-up actions, please contact Compounding@fda.hhs.gov. Please reference in the Email Subject "State Action Letter" and the name of the state-licensed pharmacy.

Sincerely,

Hidee L. Molina -S

Digitally signed by Hidee L. Molina -S
Date: 2023.07.13 08:53:34 -04'00'

Hidee Molina
Division Director
Division of Compounding I
Office of Compounding Quality and Compliance
US. Food and Drug Administration

Attachments: Redacted copies of Form FDA 483 issued on April 15, 2016, April 29, 2019, and July 26, 2021.

Cc: Svetislav Milic, RPh, Pharmacist-in-Charge/Owner

Colonia Care Pharmacy
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