FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA EMAIL CONFIRMED DELIVERY

February 13, 2023

Kamlesh Gandhi
Executive Director
Arizona State Board of Pharmacy
PO Box 18520
Phoenix, AZ 85005

Dear Dr. Gandhi,

The purpose of this letter is to refer to you, the Arizona State Board of Pharmacy for appropriate follow up, the U.S. Food and Drug Administration's concerns about poor sterile practices observed during an FDA inspection at a pharmacy you licensed, First Royal Care Co. LLC, dba Red Mountain Compounding Pharmacy, located at 6828 E. Brown Rd., Ste 101, Mesa, AZ 85207, FEI: 3015235235.

The FDA inspected the firm from August 29, 2022, to September 12, 2022. You were informed of the inspection but did not accompany FDA investigators 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/media/164854/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 the FDA will provide to the firm, which contains additional information about our inspection. 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 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for drug products compounded by First Royal Care Co. LLC, dba Red Mountain Compounding Pharmacy and the FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

During the inspection, the FDA investigator observed deviations from appropriate 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 perform dynamic smoke studies for their ISO Class 5 LAFW

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(laminar airflow workstation), which is used to produce all hazardous (hormone) sterile drug products since approximately April 2022. In addition on 09/01/22 the lead sterile technician stated they sealed a circular opening on the back panel of the ISO Class 5 LAFW when it was installed around April 2022. No studies have been performed to ensure the sealed opening does not leak or disrupt laminar airflow. Since approximately 05/31/2022, the firm has produced and dispensed hazardous sterile drug products using this ISO Class 5 LAFW.

2. The back panel of the ISO Class 5 LAFW, which is used to produce all hazardous (hormone) sterile drug products since approximately April 2022, was observed to be difficult to clean. On 09/01/22, the lead sterile technician stated that the surface is used to cover the mounting holes of lamps. ISO class 5 equipment should be completely smooth and easy to clean.

3. The firm's procedure titled Cleanroom Equipment Cleaning, version one, dated 03/18/22, does not include a deactivation agent when cleaning equipment and utensils used to produce hazardous sterile drug products. The equipment and utensils are non-dedicated and are used to produce both hazardous and non-hazarous sterile drug products. Since approximately 05/31/2022, the firm has produced and dispensed sterile drug products, which include hazardous sterile drug products.

First Royal Care Co. LLC, dba Red Mountain Compounding Pharmacy committed to the FDA in its response to the Form FDA 483, dated September 30, 2022, 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 records, the FDA does not intend to take further action at this time with regard to the findings of this inspection. The FDA believes that the corrective actions can be appropriately overseen by the State of Arizona. Therefore, the FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the State, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with drug products 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 Andrew Haack, compliance officer, at 206-340-8212, or by email at Andrew.Haack@fda.hhs.gov. Please reference the FEI number cited above when contacting us.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP: ah

Cc: Dawn T. Hoang
Co-owner
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