DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100 Industry Information: www fda.gov/oc/industry	08/29/2021 - 09/12/2022* FEI NUMBER 3015235235

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dawn T. Hoang, PharmD. & Co-Owner

FIRM NAME	STREET ADDRESS
First Royal Care Co. LLC, dba Red Mountain Compounding	6828 E Brown Rd Ste 101
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Mesa, AZ 85207-3761	Producer of Sterile and Non-Sterile Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1:
ISO-5 classified areas were not certified under dynamic conditions. Specifically, uni-directional airflow was not verified under operational conditions.

You never performed any dynamic smoke studies for your (b) (4) ISO Class 5 LAFW (laminar airflow workstation), model number (b) (4) serial number (b) (4), which is used to produce all hazardous (hormone) sterile drug products since approximately April 2022. In addition, on 09/01/22, your Lead Sterile Technician stated (b) (6) sealed the approximate (b) (4) inch circular opening on the back panel of the (b) (4) ISO Class 5 LAFW with (b) (4) 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 05/31/22, your firm has produced and dispensed approximately (b) (4) lots of hazardous sterile drug products using this ISO Class 5 LAWF.

OBSERVATION 2:
The ISO 5 classified equipment has difficult to clean surfaces.

Specifically, I observed (b) (4) on the back panel of your (b) (4) ISO Class 5 LAFW (laminar airflow workstation), model number (b) (4), serial number (b) (4), which is used to produce all hazardous (hormone) sterile drug products since approximately April 2022. On 09/01/22, your Lead Sterile Technician stated the (b) (4) is used to cover the mounting holes for (b) (4) lamps. ISO class 5 equipment surfaces should be completely smooth and easy to clean.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Christopher M. Jenner -S Digitally signed by Christopher M. Jenner -S Date: 2022.09.12 10:17:13 -07'00'	Christopher M. Jenner, Investigator	09/12/2022

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OBSERVATION 3:
Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, your written procedure titled Cleanroom Equipment Cleaning, SOP: (b) (4), 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-hazardous sterile drug products. Since approximately 05/31/22, your firm has produced and dispensed approximately (b) (4) lots of sterile drug products which include approximately (b) (4) lots of hazardous sterile drug products.

*Date(s) of Inspection: 08/29/22 (MON), 08/30/22 (TUE), 08/31/22 (WED), 09/01/22 (THU), 09/06/22 (TUE), 09/12/22 (MON)

Add Continuation Page

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE		Christopher M. Jenner, Investigator	09/12/2022

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."