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

UNTITLED LETTER

VIA EMAIL CONFIRMED DELIVERY

April 27, 2023

Payam Zarrabizadeh, Owner
A1Rx LLC dba Rx Unlimited Pharmacy
16673 Roscoe Blvd
North Hills, CA 91343-6109
(b) (6), (b) (7)(C)

Dear Mr. Zarrabizadeh:

From October 12, 2022, to October 21, 2022, U.S. Food and Drug Administration investigators inspected your facility, A1Rx LLC dba Rx Unlimited Pharmacy, located at 16673 Roscoe Blvd, North Hills, CA 91343. During the inspection, the investigators noted deficiencies in your practices for producing drug products which put patients at risk.

The FDA issued a Form FDA 483 to your firm on October 21, 2022. The FDA acknowledges receipt of your facility's response, received on November 3, 2022. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and the FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigators observed that:

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine CA 92612-2506
Telephone: 949-608-2900
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www.fda.gov

1. Your firm handled hazardous drug products without providing adequate containment, segregation, or cleaning of work surfaces and utensils to prevent cross-contamination.

2. Your firm failed to confirm that the quality of (b) (4) was suitable for its intended use in the production of non-sterile drug products.

3. Personnel performing sterile compounding operations are inadequately gowned in order to prevent contamination of drug products intended to be sterile.

4. Vermin was observed in your production areas.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a), the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding your responses related to the insanitary conditions, some of your corrective actions appear adequate or partially adequate; however, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. You state that your firm will implement changes to your cleaning process including clarifying the cleaning process and the use of new cleaning agents. However, your firm failed to provide sufficient evidence to ensure that these new cleaning agents are effective for their intended purpose, and you have not demonstrated how cleaning practices have been corrected to sufficiently ensure the prevention of cross-contamination.

2. You state that your firm will transition to the (b) (4) for non-sterile compound preparations; however, your firm has failed to provide evidence of the implementation of this change including but not limited to the intended supplier of the component or how processes and procedures will be changed to incorporate this new component. Additionally, your firm has failed to clarify whether the (b) (4) system will be decommissioned and/or the future uses of this (b) (4) system.

3. Your firm has failed to demonstrate how you will implement effectiveness checks for gowning procedures and processes. Additionally, your responses did not provide a risk assessment or retrospective review to determine the potential impact of practices on sterile and non-sterile drug products.

4. You state that your firm has contracted the service of a pest control company; however, your response does not include information on proactive steps you will take to ensure the facility does not contain harborage areas, gaps on exterior walls, or steps to prevent doors from being left open.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time in which you will do so.

Send your electronic reply to ORAPHARM4_Responses@FDA.HHS.GOV or mail your reply to:

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food & Drug Administration
19701 Fairchild Road
Irvine, California 92612-2506

Please identify your response with unique identifier **657726**.

If you have any further questions, please contact Compliance Officer Nayan J. Patel by email at Nayan.Patel1@FDA.HHS.GOV or by phone at (303) 236-3010.

Sincerely,

(b) (6), (b) (7)(C)

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

SP: np