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

VIA UPS SIGNATURE CONFIRMED DELIVERY

October 5, 2020

Amy Frost, Pharm.D.
Pharmacist-in-Charge
OSRX, Inc.
1120 Kensington Ave., Unit E
Missoula, MT 59801-5619

Dear Dr. Frost:

From August 28, 2018, to September 7, 2018, and from April 17, 2019, to April 18, and April 25, 2019, U.S. Food and Drug Administration (FDA) investigators inspected your facility, OSRX, Inc. formerly Pinnacle Compounding, LLLP, located at 1120 Kensington Ave., Unit E, Missoula, MT, 59801. During the inspection, the investigators observed deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form 483 to your firm on April 25, 2019. FDA acknowledges receipt of your firm's response, dated May 14, 2019. Based on this inspection, it appears that you produced drugs 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 FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)]. [1]

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigators noted that drug products intended or expected to be sterile were

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

Division of Pharmaceutical Quality Operations IV
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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:

1. Your firm failed to conduct adequate post-use (b) (4) testing on (b) (4) used to sterilize drug product.

2. The investigators observed an operator spraying her gloved hands with a disinfectant directly above a tray of opened sterile vials, which were then filled with drug product.

3. The investigators observed unsealed gaps in the ceiling as well as non-cleanable surfaces and apparent rust spots within ISO-classified 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; 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. Specifically, you state that your firm revised your standard operating procedure (SOP) for (b) (4) testing used to sterilize your products, but you did not provide an updated copy of your SOP. Additionally, your firm stated that you trained your staff on the revised (b) (4) testing procedure; however, your firm failed to provide documentation of such trainings.

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.

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

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 the violations identified above 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 correct the violations. Please include an explanation of each step being taken to prevent the recurrence of the violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within thirty (30) working days, state the reason for the delay and the time within which you will complete the correction.

Please 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 responses with the unique identifier: **CMS 609457**.

If you have questions regarding the contents of this letter, please contact Mariza Jafary, Compliance Officer via email at Mariza.Jafary@fda.hhs.gov or by telephone at 949-608-2977.

Sincerely,

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

SP: mj